anticipated schedule for accommodating that demand;

"(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

"(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 6(b).

"(2) SUBSEQUENT REPORTS.—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

"(n) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall publish an annual plan that—

"(1) identifies the chemical substances for which risk evaluations are expected to be completed that year and the resources necessary for their completion;

Commented [A45]: "the completion of the risk evaluations." - SLC

"(2) describes the status of each risk evaluation that has been initiated but not yet completed; and

"(3) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

"(o) CONSULTATION WITH SCIENCE ADVISORY COMMITTEE ON CHEMICALS.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish an advisory committee, to be known as the Science Advisory Committee on Chemicals (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

Commented [A46]: "on" in SLC version

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women,

Commented [A47]: "at a minimum" – SLC version

children, and other potentially exposed or susceptible subpopulations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(p) PRIOR ACTIONS.—

"(1) RULES, ORDERS, AND EXEMPTIONS.—Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(2) PRIOR-INITIATED EVALUATIONS.—Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator under this section or section 6.

"(3) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES, PROCEDURES, AND GUIDANCE.—

Commented [A48]: SLC treats (p)(1) as a separate subsection; treats (p)(2) and (p)(3) as (q)(1) and (q)(2).

Commented [A49]: "this Act" – SLC version

Commented [A50]: "this Act" – SLC version

Commented [A51]: "established" – SLC version

N

Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule under this Act solely because the action was completed prior to the development of a policy, procedure, or guidance under subsection (l).".

Commented [A52]: "this Act, or the amendments made by this Act" – SLC version

Commented [A53]: Not in SLC version

HLC clarification seems correct.

Commented [A54]: "completion" in SLC version

Commented [A55]: "new" in SLC version

Commented [A56]: SLC says "under this section or section 6"

This is a significant discrepancy. Just referring to subsection (l) would be sending a very definite signal that Congress intended other policies and procedures (i.e,. those established under 6) to give rise to obligations to revise or withdraw completed risk evaluations, determinations, and rules that were developed prior to the policies and procedures being finished.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 10:15:42 PM
To: 'Foster, Lakecia (Durbin)' [Lakecia_Foster@durbin.senate.gov]
Subject: Sen. Durbin TA Request on draft Lead-Safe Housing for Kids Act
Attachments: MIR16129_XML.DOC

Kecia,
This responds to your technical assistance request on the draft lead paint bill.

Page 1, line 24-25: the term "in accordance with the best available science" is unclear as to what criteria EPA should use to update, e.g., health based?

Page 2, line 25-26: "require a risk assessment for all housing receiving Federal assistance" A risk assessment reflects current conditions only. Lead paint is not static; a hazardous condition could emerge the day after a clean risk assessment. Note that without regular (e.g., annual) followup checks, this is unlikely to result in reliable risk reduction.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Wednesday, March 02, 2016 1:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Sven- thanks for arranging the call. Here's the latest draft from leg counsel. It does not include the changes HUD made to this draft, which I am working on incorporating. The EPA section is under Sec. 3 and a reference in the GAO report. However, it does not include amending the lead-based paint definition. We were thinking of adding lead-contaminated paint under Section 3 with the other standards, but that may not be the way to go.

It would be helpful to get TA on directing the standard to be evaluated to see if should be updated based on the best available science.

If I could be get something before COB today, that would be great. Working on a tight timeline.

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building

202-224-2152

From: Foster, Lakecia (Durbin)
Sent: Wednesday, March 02, 2016 10:07 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Great. Thanks!

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 10:06 AM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: Re: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia- let's have a call at 1pm. Please call 866-299-3188, code 202-566-2753#. Please let me know if any questions.
Thanks,
Sven

On Mar 2, 2016, at 9:57 AM, Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov> wrote:

Sven- Yes! I'm available between 10-11 am and between 11:30-1:30. If these time's don't work, I can find another time.

Thanks for your quick turnaround on this.

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 9:51 AM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia – in response to your TA request on lead-based paint - any time available today for a quick phone call to discuss? We use different terms than the ones you indicate and I want to loop in key program folks to answer your questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Tuesday, March 01, 2016 5:54 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Thanks.

We have some advocates that are interested in aligning the CPSC definition of lead-based paint with the one under the Lead-Based Paint Poisoning Prevention Act. I would like to know the difference in the definitions and why they are differ. I also would like to know what would be the impact of changing to the lower standard. Also, is there a difference between the definition and EPA's regulations on lead-contaminated paint?

We are finalizing text tomorrow for introduction on Thursday. Sorry for the late notice, but it is an issue that came up on my call with HUD today.

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 01, 2016 3:44 PM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: Sen. Durbin Inquiry on lead-contaminated hazards

Lakecia,
Thanks for the inquiry about lead based paint hazards. Please let me know your questions and I'll be glad to provide a response or set up a call with our lead folks. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Tuesday, March 01, 2016 2:30 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: EPA lead-contaminated hazards

Hi Sven,

My colleague, Jasmine Hunt, forwarded your contact information to me. I'm working on a bill regarding HUD lead regulations. We are also including related provisions that under EPA's jurisdiction. Do you have a moment to chat about the lead-based paint definition and EPA's regulations on lead-contaminated paint?

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

Title: To amend the Residential Lead-Based Paint Hazard Reduction Act of 1992 to define environmental intervention blood lead level, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ["Lead-Safe Housing for Kids Act of 2016"].

SEC. 2. DEFINITIONS.

In this Act—

(1) the term "Department" means the Department of Housing and Urban Development;

(2) the term "housing receiving Federal assistance" has the meaning given the term in section 35.110 of title 24, Code of Federal Regulations, or any successor thereto;

(3) the term "public housing agency" means an agency described in section 3(b)(6) of the United States Housing Act of 1937 (42 U.S.C. 1437a(b)(6));

(4) the term "residential dwelling" has the meaning given the terms in section 1004 of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851b); and

(5) the term "Secretary" means the Secretary of Housing and Urban Development.

SEC. 3. UPDATES TO LEAD-CONTAMINATED DUST AND LEAD-CONTAMINATED SOIL STANDARDS.

(a) EPA Regulations.—The Administrator of the Environmental Protection Agency, in consultation with the Director of the Centers for Disease Control and Prevention, shall promulgate regulations to update the standards for lead-contaminated dust and lead-contaminated soil under part 745 of title 40, Code of Federal Regulations, in accordance with the best available science.

(b) HUD Regulations.—The Secretary shall promulgate regulations to update the standards for lead-contaminated dust and lead-contaminated soil under part 35 of title 24, Code of Federal Regulations, in accordance with the regulations promulgated by the Administrator of the Environmental Protection Agency under subsection (a).

SEC. 4. AMENDMENTS TO RESIDENTIAL LEAD-BASED PAINT HAZARD REDUCTION ACT OF 1992.

(a) In General.—Section 1017 of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4852c) is amended—

(1) by striking "Not later than" and inserting "(a) In General.—Not later than"; and

(2) by adding at the end the following:

"(b) Environmental Intervention Blood Lead Level.—

"(1) IN GENERAL.—For purposes of this title and any regulations issued under this title, an environmental intervention blood lead level means the lower of—

"(A) 5 ug/dL (micrograms of lead per deciliter);

"(B) the blood level reference value based on the 97.5th percentile of the population blood lead level in children ages 1 through 5 in the National Health and Nutrition Examination Survey and as recommended by the Centers for Disease Control and Prevention; or

"(C) the most recent definition for elevated blood lead level set by the Centers for Disease Control and Prevention.

"(2) RELATION TO OTHER AUTHORITIES.—Nothing in this Act may be construed to affect the authority of the Environmental Protection Agency under section 403 of the Toxic Substances Control Act (15 U.S.C. 2683).".

(b) Regulations.—Not later than 90 days after the date of enactment of this Act, the Secretary shall amend the regulations of the Department to comply with the amendments made by subsection (a).

SEC. 5. AMENDMENTS TO THE LEAD-BASED PAINT POISONING PREVENTION ACT.

Section 302(a) of the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4822(a)) is amended by adding at the end the following:

"(5) ADDITIONAL PROCEDURES FOR FAMILIES WITH CHILDREN UNDER THE AGE OF 6.—

"(A) RISK ASSESSMENT.—

"(i) IN GENERAL.—Not later than 90 days after the date of enactment of the [Lead-Safe Housing for Kids Act of 2016], the Secretary shall promulgate final regulations that—

"(I) require a risk assessment for all housing receiving Federal assistance described in paragraph (1) with respect to an initial inspection of a dwelling unit constructed prior to 1978 for lead-based paint and lead-based paint hazards prior to the occupancy by a family with a child of less than 6 years of age; and

"(II) provide that a visual assessment is not sufficient for purposes of complying with clause (i).

"(ii) EXCEPTION.—The final regulations promulgated under clause (i) shall provide an exception to the requirement under subclause (I) of such clause for dwelling units where the owner of the dwelling unit provides the Secretary with a certification or other proof that the dwelling unit is lead-free.

"(B) RELOCATION.—Not later than 90 days after the date of enactment of the [Lead-Safe Housing for Kids Act of 2016], the Secretary shall promulgate final regulations to provide that a family with a child of less than 6 years of age that occupies a dwelling unit in housing receiving Federal assistance described in paragraph (1) may relocate on

an emergency basis and without placement on any waitlist to another such dwelling unit without penalty or lapse in assistance if—

"(i) lead-based hazards were identified in the dwelling unit; or

"(ii)(I) lead-based hazards were identified in the dwelling unit; and

"(II) the environmental intervention blood lead level for the child exceeds the value described in section 1017(b) of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4852c(b))."

SEC. 6. GAO REPORT ON LEAD HAZARDS IN FEDERALLY ASSISTED HOUSING.

Not later than 180 days after the date of enactment of this Act, the Secretary shall submit to Congress a report on lead hazards in housing receiving Federal assistance, which shall—

(1) analyze the implications of—

(A) changing Department regulations to align with the Centers for Disease Control and Prevention standards; and

(B) requiring a risk assessment (beyond a visual assessment) for initial and periodic inspections for lead hazards for all housing receiving Federal assistance, primarily residential dwellings receiving assistance under section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f), and the impact it would have on landlord participation and the stock of affordable housing;

(2)(A) evaluate whether the current definition of lead-based paint is in accordance with the best available science; and

(B) provide recommendations to the Environmental Protection Agency on updating the relevant standards of that agency;

(3) analyze whether existing Federal programs and Federal funding for lead abatement activities in housing receiving Federal assistance meet the current and evolving needs, and if not, the merits of identifying or creating set-asides within those Federal programs to conduct lead abatement activities;

(4) evaluate the cost of lead prevention and abatement activities and provide recommendations on how to improve coordination and leveraging of public and private funds, including private investments and tax incentives, to reduce the cost associated with the identification and remediation of lead hazards and expedite home remediation;

(5) identify existing partnerships with public housing agencies and public health agencies in addressing lead hazards, what gaps exist in compliance and enforcement, and whether the partnerships can be replicated and enhanced with dedicated funding and better data collection and dissemination among stakeholders; and

(6) examine the appropriateness and efficacy of existing Department protocols on reducing or abating lead hazards and whether they are aligned with specific environmental health scenarios to ensure the best and appropriate health outcomes and reduce further exposure.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act and the amendments made by this Act such sums as may be necessary for each of fiscal years 2017 through 2021.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 6:00:19 PM
To: Adrian_Deveny@merkley.senate.gov
Subject: Sen. Merkley TSCA TA on state waiver.

Adrian,
This responds to the request on state preemption waivers.

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

No, because it doesn't clearly account for the fact that there are two different actions at issue: First, there is the action for which the state is seeking a preemption waiver; Second, there is the proposed or final *preliminary* action that predated EPA's scope publication, which is the basis for the state being entitled to the preemption waiver. What links the actions is that they relate to the same chemical substance, but there is no such linking language in the current draft. Also, the reference to a "draft" action should really be a reference to a "proposed" action. Here's the revised language, in context:

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

…

> **(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is for the prioritization, assessment, or management of such chemical substance or is otherwise related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.**

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on prioriziation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Deleting the words would make the passage less likely to function in the manner you intend. The phrase "prioritization, assessment, or management" helps to illustrate what you mean by an action

that is "related to the effects of exposure." Even though the illustrative list is just a subset of what is already included under the heading of "related to," an illustrative list helps to guard against courts later construing "related to" more narrowly than you intend (e.g., deciding that prioritization can't be related to the effects of exposure because the state hasn't yet definitively figured out what those effects are at the stage of prioritization).

Section 18(f)(2) Required Exemptions.—

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Date: April 14, 2016 at 9:44:32 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA on waiver

Sven

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on priorization and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Section 18(f)(2) Required Exemptions.—

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 6:39:24 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: section 4

Michal – got it – thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 05, 2016 2:34 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: section 4

Sven

Attached is a new Section 4 that we need TA on. Generally, it can be described as:

- Existing TSCA 4(a)(1) and 4(a)(2) (mostly)
- In addition to that, Senate text on other circumstances that allow testing, by rule or order or consent agreement
- Other changes to things like ITC and 4(f) that have been discussed/proposed by various parties
- All (I hope) the conforming changes the House offer removed or didn't do

Please give it a careful read and let us know of any issues.

Senate colleagues – note I did not strike and replace the animal testing language but just bracketed it to reflect ongoing discussions. Let me know if you want a different approach there.

Thanks
michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 7:54:10 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on PBT - revised draft
Attachments: Markey. TSCA TA.PBT (4-12).docx

Michal – the attached TA responds to the request on the revised draft PBT language.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

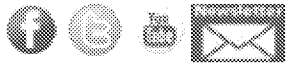
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 8:38 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on PBT - revised draft

Can you suggest a way to assist on the first question? I am trying as hard as I can to get you fees for exposure assessments, I'm definitely not ignoring that concern.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 12, 2016 6:57 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on PBT - revised draft

Michal,

This TA responds to the follow up request on PBTs.

We reviewed the attached revised version and still have a difficult time understanding how EPA would be expected to operate under this provision. The language makes clear that for identified PBTs, EPA would propose rules that both protect against unreasonable risks and "reduce exposure to the extent practicable." The language also states that risk evaluations are not required for the identified chemicals. We see the two statements as irreconcilable. EPA determines "unreasonable risk" by doing a risk evaluation on a chemical. Without knowing whether and how the chemical presents an "unreasonable risk," EPA would be unable to draft a rule "in accordance with subsection (a)."

We'd also note that in the absence of risk evaluation under Section 6, there's no associated fee collection authority under Section 26.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 3:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: 04-12-16PBT (Conf Proposal)d.docx

See if this works on pbts

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

ALL CITATIONS AND CROSS-REFERENCES ARE TO SECTION 6 AS IT APPEARS IN THE SENATE OFFER

( ) Chemicals That Are Persistent, Bioaccumulative, and Toxic.--

(1) Expedited Action.--Not later than 3.1 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose a rules underin accordance with subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments —

(A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4 prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

(B) exposure to which under the conditions of use is likely to the general population, a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) Prior to issuing the proposed rules required by paragraph (1), the Administrator shall conduct risk evaluations for the subject chemical substances pursuant to section 6(b)(4), except that section 6(b)(4)(H) shall not apply. Such risk evaluations shall count toward the number of risk evaluations required to be conducted under section 6(b)(2). ~~Except as provided in paragraph (5), the Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to this subsection.~~

(3) Final Rules.--Notwithstanding subsections (__),subject to subsections __ and __ , not later than 18 months after proposing a rules under paragraph (1), the Administrator shall promulgate final rules underin accordance with subsection (a).

(4) Each proposed and final rule required by paragraphs (1) and (3) shall be developed in accordance with section 6(c)(2), (3) and (4). Each such proposed and final rule shall ensure that the subject chemical substance does not present any unreasonable risk of injury to health or the environment that the Administrator determines the chemical substance presents in the risk evaluation under section 6(b)(4), and shall reduce exposure to the substance to the extent practicable. ~~, In selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a) the Administrator shall, for each chemical substance for which a rule is proposed under paragraph (1), reduce exposure to the substance to the extent practicable.~~

(5) Alternative approach~~Relationship to subsection (b).~~ ~~—~~Within 3 months (?) of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall

Commented [A1]: This is based on three years for the risk evaluation (the timeframe allowed in section 6(b)(4)(G)(i) of senate offer, without the opportunity to extend by a year afforded in (G)(ii), plus one year for the proposal, per sec 6(c)(1)(A), without the opportunity to extend afforded in 6(c)(3).

Commented [A2]: Presumably EPA is not required to address these chemicals in a single rulemaking, so long as EPA meets the 4-year deadline.

Commented [A3]: This is the requirement for notice and comment on risk evaluations. .

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Commented [A4]: This subjects these rulemakings to the required consideration provisions (including cost) and articles and replacement part provisions for 6(a) rules (6(c)(2)), and the rulemaking procedure provision (6(c)(3) and (4)). It does not include the deadline provision (6(c)(1)) because deadlines are handled in this provision.

NOTE TO EPA REVIEWERS: An argument could be made that EPA should not be saddled with all of the 6(c)(2) requirements under a rule where we are merely reducing exposure. Eg, it is not clear why EPA could consider the effects of the substance on health and the environment, and factor those considerations in to the selection of restrictions, under such a rule. That said, it seems more complicated than it's trying to apply (c) to one set of rules and not another.

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~~identify the chemical substances that are subject to paragraph (1). If,~~ within 3 months ~~[?]~~ of ~~such identification at any time prior to the date that is 90 days after the date on which the Administrator proposes the rule under paragraph (1), the Administrator makes a finding under subsection (___), or~~ a manufacturer requests a risk evaluation under subsection (__), with respect to ~~such a~~ chemical substance, such chemical substance shall not be subject to this subsection, except that any proposed or final rule promulgated in accordance with section 6(a) for such chemical substance shall ensure that the chemical substance does not present an unreasonable risk of injury to health or the environment and reduce exposure to the substance to the extent practicable.

Commented [A5]: How will they know? Could drop this.

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Commented [A6]: As edited, this provision now just removes these PBTs from the front of the queu.

(5) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

(A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—

(i) chemical substances that, with respect to persistence and bioaccumulation, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system) ;and

(ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

(C) For a chemical substance subject to subsection (a) that with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system) the proposed and final rules shall ~~Administrator shall~~ ensure that the chemical substance does not present an unreasonable risk of injury to health or the environment and reduce exposure to the substance to the extent practicable, ~~in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), reduce exposure to the substance to the extent practicable.~~

Commented [A7]: As edited, this provision now just removes these PBTs from the front of the queue.

Retain expedited action provision in 6(c)

(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the

publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Commented [A8]: This will not apply to PBTs subject to expedited action under (1), because that provides its own deadline, which would not be extended by this provision allowing extension of 6(c) deadlines. Extension authority for these chems would have to be provided in this PCB section – could be relatively easily drafted if desired.

In addition, some conforming changes in section 6 would need to be made or considered in view of this new PBT provision. The parenthetical phrase addressing PBTs at the end of section 6(b)(2)(A) presumably should be stricken, since this new PBT provision establishes a stronger priority for PBTs. Also, consider whether the parenthetical at the end of 6(b)(2)(B) re PBTs should be dropped, on the grounds that there will not be enough PBTs left to fill the 50% quota. Also, 6(b)(2)(D)(i) may be obsolete for a similar reason.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/24/2016 4:39:05 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - section 12

Michal – got it - thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 24, 2016 11:33 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - section 12

Sven

Other than fixing the "unreasonable risks" in section 12 (and the Hg language added en route to the Floor), does EPA see any workability or other problems associated with leaving section 12 the way it is in existing statute rather than the changed version in 697?

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/28/2016 10:12:01 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: Re: TA request on TSCA section 5

Thanks- will do

On Apr 28, 2016, at 6:09 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

As soon as you can. Tomorrow morning at the latest.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 28, 2016 6:06 PM
To: Couri, Jerry
Subject: Re: TA request on TSCA section 5

Jerry- got it- checking. How soon needed? Thanks,
Sven

On Apr 28, 2016, at 5:53 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Sven:

Thanks to you and the folks at EPA for the TA on section 5. We have a follow-up question on what you sent to us:

If we change the wording in proposed new section 5(a)(3)(B) to match existing section 5(e) -- as I think the Agency's TA suggests, would we need to change the lead in to existing 5(e)?

Thanks.

<!--[if !supportLists]--><!--[endif]-->Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)
<image001.png><image002.png><image003.png><image004.png><image005.png>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/17/2016 11:31:12 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on Section 6 cost considerations

Michal - this got put on the side. Will get it going pronto. Thanks,
Sven

On Mar 17, 2016, at 5:45 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Good morning

It is possible we will start a section 6 discussion today. Is this getting close?

M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, March 8, 2016 11:21 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 cost considerations

Michal – got it (late catch). Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 07, 2016 2:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - Section 6 cost considerations

In the same spirit and on the same timeframe as the others I've sent today, can this redline to what was sent to the House last week AND the version of the language that was sent to the House last week be ranked/added to the table from the 01/05/16 TA?

Thanks
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 10:12:46 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: TSCA TA: follow up re section 5 - "or otherwise necessary"

Michal, Jonathan, and Adrian,
We understand that the question is whether the phrase "or as otherwise necessary" should be inserted after "submitter."

We just spoke to Dmitri, Richard Denison and Mike Walls about this. We do not think this addition is necessary, since EPA would have no need to unilaterally extend the review period to require testing. If the submitter does not agree to an extension, then the review period would lapse without and (a)(3)(A) determination or an (e) order, and manufacture and processing could not commence.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

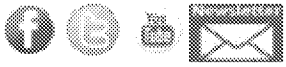
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 19, 2016 4:41 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: as a follow up re section 5

We specifically want your view on the following change

Page 8 line 5 – Insert "or as otherwise necessary" after "matter[Z1] [Z2] "

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 6:43:08 PM
To: 'Foster, Lakecia (Durbin)' [Lakecia_Foster@durbin.senate.gov]
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia – thanks for sending over the TA request. I'll see what we can get you tonight. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Wednesday, March 02, 2016 1:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Sven- thanks for arranging the call. Here's the latest draft from leg counsel. It does not include the changes HUD made to this draft, which I am working on incorporating. The EPA section is under Sec. 3 and a reference in the GAO report. However, it does not include amending the lead-based paint definition. We were thinking of adding lead-contaminated paint under Section 3 with the other standards, but that may not be the way to go.

It would be helpful to get TA on directing the standard to be evaluated to see if should be updated based on the best available science.

If I could be get something before COB today, that would be great. Working on a tight timeline.

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Foster, Lakecia (Durbin)
Sent: Wednesday, March 02, 2016 10:07 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Great. Thanks!

Lakecia Foster
Economic Policy Advisor

U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 10:06 AM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: Re: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia- let's have a call at 1pm. Please call 866-299-3188, code 202-566-2753#. Please let me know if any questions.
Thanks,
Sven

On Mar 2, 2016, at 9:57 AM, Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov> wrote:

Sven- Yes! I'm available between 10-11 am and between 11:30-1:30. If these time's don't work, I can find another time.

Thanks for your quick turnaround on this.

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 9:51 AM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia – in response to your TA request on lead-based paint - any time available today for a quick phone call to discuss? We use different terms than the ones you indicate and I want to loop in key program folks to answer your questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Tuesday, March 01, 2016 5:54 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Thanks.

We have some advocates that are interested in aligning the CPSC definition of lead-based paint with the one under the Lead-Based Paint Poisoning Prevention Act. I would like to know the difference in

the definitions and why they are differ. I also would like to know what would be the impact of changing to the lower standard. Also, is there a difference between the definition and EPA's regulations on lead-contaminated paint?

We are finalizing text tomorrow for introduction on Thursday. Sorry for the late notice, but it is an issue that came up on my call with HUD today.

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 01, 2016 3:44 PM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: Sen. Durbin Inquiry on lead-contaminated hazards

Lakecia,
Thanks for the inquiry about lead based paint hazards. Please let me know your questions and I'll be glad to provide a response or set up a call with our lead folks. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Tuesday, March 01, 2016 2:30 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: EPA lead-contaminated hazards

Hi Sven,

My colleague, Jasmine Hunt, forwarded your contact information to me. I'm working on a bill regarding HUD lead regulations. We are also including related provisions that under EPA's jurisdiction. Do you have a moment to chat about the lead-based paint definition and EPA's regulations on lead-contaminated paint?

Thanks,
Kecia

Lakecia Foster

Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 5:02:04 PM
To: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Sen. Merkley TSCA TA request on waiver

Adrian- thanks for the reminder. We're working on it and should have something for you shortly. Best,
Sven

On Apr 15, 2016, at 1:00 PM, Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov> wrote:

Sven-. Any progress here? We need this today.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Thursday, April 14, 2016 9:52 PM
To: Deveny, Adrian (Merkley)
Subject: Sen. Merkley TSCA TA request on waiver

Adrian,
Thanks for the TA request. I'll get it to folks to get a response. Please let me know if any additional questions.
Thanks,
Sven

On Apr 14, 2016, at 9:44 PM, Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov> wrote:

Sven
Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.
First, does this language accomplish this objective?
Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on priorizaition and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Section 18(f)(2) Required Exemptions.—

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 1:13:14 AM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Sen. Markey TSCA TA on House section 6 (4-22)
Attachments: Markey.TSCA TA.House Section 6 (4-22).docx; ATT00001.htm

Michal,
This TA responds to the request on House section 6 (4-22).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

We have just one bit of TA on the April 22 HLC draft of section 6:

- Complex consumer goods are now defined as having multiple parts, not 50 parts. Since this would mean that electronic or mechanical devices with 2 or more parts fall within the definition, one may as well drop the numerical criterion.

Here are some additional observations about this version, which we point out but have no technical concerns with. The draft:

-- Drops from 6(a) the reference to PBTs, thereby avoiding potential confusion about the rulemaking standard.

-- Makes both active and inactive substances subject to prioritization

-- Makes low priority dependent on a "likely not to present" finding

-- Strikes much of (b)(2)(C), which had provided direction for continuing prioritization and risk evaluation after 3-1/2 years; the dropping of this text eliminates the provision requiring that all work plan chemicals undergo risk evaluation, and the awkwardness of prioritizing with a foreordained outcome.

-- Retains the requirement for EPA to do a prioritization rule, but eliminates the requirement for notice and comment in prioritization and the required deadlines for prioritization

-- Strikes the requirement for notice and comment on industry requests for risk evaluations

-- Drops the specification that EPA must consider quantified and unquantified costs and benefits in rulemaking, and just instructs EPA to consider costs and benefits

-- Includes 6(c)(2)(C) -- the provision that requires EPA to consider whether feasible alternatives are available in deciding whether to ban or severely restrict and that had been dropped from the preceding draft. The consideration is now limited "to the extent practicable", which had not been in the previous version

-- Amends 6(c)(2)(E) to make it easier for EPA to regulate articles. EPA must show that such regulation is necessary to address identified risks, but need not show that the risks come from the article or category of articles.

We are not troubled by the elimination of required timeframes for prioritization, or by the dropping of the requirement in (b)(2)(C) to keep prioritizing and evaluating until the priority of

all active substances has been designated, because we think continued throughput is secured by the following provisions:

- The requirement to have at least 20 high-priority substances undergoing risk evaluation within 3-1/2 years in (b)(2)(B),
- The deadlines for risk evaluations ((b)(4)(G)) and the requirement to initiate risk evaluation "upon designating a chemical substance as high-priority" ((b)(3)(A)), and
- The requirement to add a high-priority chemical for each completion of a risk evaluation on a high-priority chemical ((b)(3)(C)).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 5:44:55 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: SEPW TSCA TA call on CBI

Got it

On Apr 5, 2016, at 1:42 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Scrap this request, as mentioned on today's phone call. We are sending something else.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Black, Jonathan (Tom Udall)
Sent: Tuesday, April 5, 2016 9:14 AM
To: Kaiser.Sven-Erik@epamail.epa.gov
Subject: FW: SEPW TSCA TA call on CBI

Sven, Dimitri shared these views with me, which is helpful.

I saw earlier EPA TA on the intro's to subsection (b) and others. I believe we've taken a stab at reworking it. not sure if Michal has run it by you yet, but wondering if it alleviates the earlier concerns.

<image001.png>

From: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Sent: Monday, April 4, 2016 10:13 PM
To: Karakitsos, Dimitri (EPW)
Subject: Re: SEPW TSCA TA call on CBI

Dimitri- we're fine with the language. It works and looks consistent with our TA. Please let me know if any questions.
Thanks,
Sven

On Apr 4, 2016, at 5:01 PM, Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven – just wanted to send this to you to confirm from the call that this works and would be consistent with previous TA as well as TA from the call. Thanks

(1) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE Subsection (a) does not prohibit the disclosure of

(A) A risk evaluation conducted under section 6.
(B) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.
(C) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry

or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section, that is not information described in subsections (c)(1) or (c)(2) or information required to be disclosed through subsection (c)(4) and is submitted with or contained in information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 04, 2016 3:39 PM
To: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA TA call on CBI

Dimitri – 4 is the earliest we can do it -- please call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, April 04, 2016 3:31 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: can we do a quick

Yup that should be fine, if you all want to call and can any earlier I will be here.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 04, 2016 3:31 PM
To: Karakitsos, Dimitri (EPW)
Subject: RE: can we do a quick

Dimitri - Checking – I think we can do 4pm – ok?

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, April 04, 2016 3:29 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: can we do a quick

5 min call on this cbi paragraph when you get a chance please? I am available now if your folks are and can be reached at my desk – 224-9705

(1) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section, that is not information described in subsections (c)(1) or (c)(2) or information described in subsection (c)(4) for which the protection from disclosure is presumed to no longer apply, and is submitted with or contained in information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 7:18:13 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on section 6

Got it - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 13, 2016 3:16 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on section 6

Do PBT, 5, 6, THEN 14

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 13, 2016 3:15 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 6

Michal – thanks for the request on section 6. Timing? We've got PBT, 5 and 14 in the queue. Best, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 13, 2016 3:13 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 6

Sven

This is HLC section 6. Pls take a look.

Thanks
M

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/24/2016 4:35:49 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request - Section 8/14 - false claims on CBI

Michal,
Got it. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 24, 2016 11:28 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 8/14 - false claims on CBI

Sven

Has EPA ever enforced against a company for making a false CBI claim?

Is there sufficient authority under 697 for EPA to do so? Does requiring companies to certify their CBI claims alter existing enforcement authority?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 8:24:53 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on PBTs

Got it - thanks

On Apr 8, 2016, at 4:12 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks. For context, we are working through the potential for a hybrid House-Senate PBT provision for section 6 that would downselect some of the high pbts from the TSCA workplan and send them straight to risk management. In addition to metals/metal compounds, there is a suggestion that these 3 should perhaps be excluded because EPA is already looking at them enough to basically be able to say "they've already done a bunch of what would go into the risk evaluation, so they should continue on the path they're on". That rationale seems perhaps to be solid for the first 2 – do you agree? What about the 3rd? would you need that data to go to risk management anyway?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 08, 2016 4:06 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on PBTs

Michal,
This responds to the TA request on PBTs.

Chlorinated paraffins:

The medium and long-chain chlorinated paraffins are being reviewed under Section 5. (Short-chain CPs have been taken off the market). Because of the high level of interest in these chemicals, EPA published an assessment in Dec. 2015 with a request for additional information on downstream uses of the chemicals. The comment period closed on March 23d, and we are currently reviewing comments.

HBCD:

EPA published a Work Plan Problem Formulation for comment in August 2015. We are developing a draft assessment and hope to publish this summer.

D4Siloxane:

We are not assessing at this time. We entered into an Enforceable Consent Agreement under section 4 to obtain monitoring and environmental fate data to inform an assessment. The work is underway now through fall to develop the data and we expect to receive it in 2017.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 08, 2016 1:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request on PBTs

Chlorinated paraffins
HBCD
D4siloxane

For these - I'm told EPA is doing risk assessment-like work on these. How far into the process are you for each of these?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2016 11:38:50 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Market TSCA TA on section 14(e)(9)

Michal- got it. Thanks,
Sven

On Mar 16, 2016, at 7:08 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

<!--[if !supportAnnotations]--> <!--[endif]-->
You're recommending restoration of the text below

> ~~In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.~~<!--[if !supportAnnotations]-->[MF1]<!--[endif]-->

But 14(a) says that EPA can't disclose anything that is exempt from disclosure under 552(a) of title 5 under exemption (b)(4).

If EPA can't release something that is FOIA-exempt under section 14, how would there be an instance in which EPA released something that would subsequently be withheld under FOIA? I'm just reading this as circular and am going to need to be able to explain it to others if I am going to be able to undo the deletion.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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<!--[if !supportAnnotations]-->

<!--[endif]-->

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 9:20:15 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: TSCA TA request on revised House section 5 (4-18)
Attachments: Section 5 (HLC) 4 18 26 OGC.docx; ATT00001.htm

Michal- revised house section 5 TA

This version addresses the comments we had on the version we sent out yesterday but introduces a number of new issues.

****This is a RLSO of Section 5, comparing HLC version timestamped April 12, 2016 at 1:50pm to HLC version timestamped April, 18, 2016 at 3:38pm.**

[DISCUSSION DRAFT]

SEC. ll. MANUFACTURING AND PROCESSING NOTICES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "Except as provided in" and inserting "(A) Except as provided in subparagraph (B) of this paragraph and";

(ii) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(iii) by striking all that follows "significant new use" and inserting a period; and

(iv) by adding at the end the following:

"(B) A person may take the actions described in subparagraph (A) if—

"(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with

subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of or imposed under subsection (b), (e), or (f); and

"(ii) the Administrator conducts a review of the notice and either—

"(I) makes a determination under paragraph (3)(A) and, as necessary, issues an order under subsection (f)(1); or

"(II) makes a determination under paragraph (3)(B) and issues an order under subsection (e)(1)(B).''; and

(B) by adding at the end the following new paragraphs:

"(3) REVIEW AND DETERMINATION.—

~~"Before the end of the applicable review period, which shall be the 90-day period for review under paragraph (1), subject to any extensions made pursuant to subsection (b), (c) or (e), and subject to section 18, the Adminstrator shall review a notice received under paragraph (1), and--"~~

Not later than 90 days after receipt of a notice under paragraph (1), subject to section 18, the Administrator shall review such notice and—

"(A) determine whether the relevant chemical substance or significant new use may

Commented [GB1]: Seems like this should refer to the applicable review period, not the 90-day period, like SLC did. Isn't that the period in which the Admininstrator must do one of these things?

present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or sus-

ceptible subpopulation identified as relevant by the Administrator under the conditions of use, and take applicable action under subsection (f) or (g); or

"(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (e).

"(4) FAILURE TO RENDER DETERMINATION.—

~~"(A) IN GENERAL.—The Administrator shall complete a review of a notice required by this section within the applicable review period~~

"(~~B~~A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Administrator shall not be relieved of any requirement to make such determination.

"(~~C~~B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the

submitter has not provided information required under subsections (b) or (e) or has otherwise

unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review.

"(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

"(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

"(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.";

(2) in subsection (b)—

(A) in the subsection heading, by striking "TEST DATA" and inserting "INFORMATION";

(B) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information"; and

(II) by striking "such data" and inserting "such information"; and

(ii) in subparagraph (B), by striking "test data" and inserting "information";

(C) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information";

(II) by striking "shall" and inserting "may"; and

(III) by striking "data prescribed" and inserting "information prescribed"; and

(ii) in subparagraph (B)—

(I) by striking "Data" and inserting "Information";

(II) by striking "data" both places it appears and inserting "information"; and

(III) by striking "show" and inserting "shows";

(D) in paragraph (3)—

(i) by striking "Data" and inserting "Information"; and

(ii) by striking "paragraph (1) or (2)" and inserting "paragraph (1) or (2) of this subsection or under subsection (e)"; and

(E) in paragraph (4)—

(i) in subparagraph (A)(i), by inserting ", without consideration of costs or other nonrisk factors" after "health or the environment"; and

(ii) in subparagraph (C), by striking ", except that" and all that follows through "subparagraph (A)";

(3) in subsection (c)—

(A) in the subsection heading, by inserting "AND REVIEW" after "NOTICE"; and

(B) by striking "before which" and all that follows through "subsection may begin";

(4) in subsection (d)—

(A) by striking "test data" in paragraph (1)(B) and inserting "information";

(B) by striking "data" each place it appears in paragraph (1)(C) and paragraph (2) and inserting "information";

(C) in paragraph (2)(B), by striking "uses or intended uses of such substance" and inserting "uses of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator"; and

(D) in paragraph (3)—

(i) by striking "for which the notification period prescribed in subsection (a), (b), or (c)" and inserting "for which the applicable review period"; and

(ii) by striking "such notification period" and inserting "such period";

(5) by amending subsection (e) to read as follows:

"(e) REGULATION WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1) If the Administrator determines that the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) for a chemical substance or significant new use with respect to which notice is required by subsection (a)—

"(A) the Administrator—

"(i) shall provide an opportunity for the submitter of the notice to submit the additional information within the applicable review period;

"(ii) may, by agreement with the submitter, extend the applicable review period for a reasonable time to allow the development and submission of the additional information under section 4; and

~~"(iii) may extend the applicable review period as necessary and promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and~~

~~"(iv) on receipt of the additional information the Administrator finds supports the determination under subsection (a)(3)(A), which shall automatically extend the review period for 90 days, shall make the determination within 90 days of receipt of the information; and~~

(iii) on receipt of the additional information complying with a rule, testing consent agreement, or order issued under section 4, may extend the review period not more than 90 days to make a decision; and

"(B) the Administrator may issue an order to take effect on the expiration of the applicable review

Commented [GB2]: Not sure this is needed, since section 4 already provides for testing for this purpose, and this suggests that EPA and the applicant cannot by agreement extend the period to allow for the submitter to voluntarily develop information. But maybe that's intended, in which case this is fine.

Commented [GB3]: (ii) refers to "applicable" review period. Either formulation seems acceptable in this context, but should be consistent.

Commented [GB4]: (iii) is different from SLC in several ways. 1. It does not require EPA to make an (a)(3)(A) determination upon receipt of information, both because it merely allows EPA to extend upon receipt of info, and if EPA does extend, merely specifies that EPA "make a decision", not "make the determination under subsection (a)(3)(A)" as SLC specified. 2. The section 4 reference seems too limiting. Even if (ii) is limited to info development under sec 4, (i) seems to contemplate voluntary submission of additional information. 3. This refers to EPA acting once information compliant with a rule, etc., is submitted, whereas SLC required action only upon receipt of information that supports the (a)(3)(A) determination.

period to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, or any combination of such activities, sufficient to allay the Administrator's initial concern that, in the absence of sufficient information, the substance or significant new use may present an unreasonable risk of injury to health or the environment.

"(2) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other nonrisk factors.

"(3) If the Administrator issues an order under paragraph (1), the submitter of the notice under subsection (a) may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection only in compliance with the restrictions specified in the order.

"(4) Not later than 90 days after issuing an order under paragraph (1), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(5) An order may not be issued under paragraph (1) respecting a chemical substance—

"(A) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c); and

"(B) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.";

(6) by amending subsection (f) to read as follows:

"(f) PROTECTION AGAINST POTENTIAL UNREASONABLE RISKS.—

"(1) ORDERS.—If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may present an unreasonable risk of injury to health or the environment in accordance with subsection (a)(3)(A)—

"(A) the Administrator shall issue an order, to take effect on or before the expiration of the applicable review period to prohibit or otherwise restrict the manufacture, processing,

distribution in commerce, use, or disposal of the chemical substance, or of the chemical substance for a significant new use, sufficient to allay the Administrator's initial concern that the substance or significant new use may present an unreasonable risk of injury to health or the environment;

"(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection except in compliance with the restrictions specified in the order; and

"(C) not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(2) SELECTING PROHIBITIONS AND RESTRICTIONS.—In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, ~~consider~~ costs and other nonrisk factors, and such an order shall include a requirement described in section 6(a).

Commented [GB5]: Any requirement? Note this this doesn't limit EPA to imposing (a) requirements, it simply seems to require that the requirements we impose have to include a 6(a) requirement. Seems kind of arbitrary.

"(3) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance that is subject to the requirements of this subsection and that the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance to the ~~maximum~~ extent practicable.

Commented [GB6]: Note deletion of "maximum" from required exposure reduction for PBTs.

"(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the

Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.";

(7) by amending subsection (g) to read as follows:

"(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment is not warranted, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing for a commercial purposes for a significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.";

(8) in subsection (h)—

Commented [GB7]: Why is this "a commercial purpose" but line 14 says "commercial purposes"? Actually, both should probably be dropped, since 5(i) defines manufacture and processing for purposes of the section to refer only to mfr and processing for commercial purposes.

(A) in paragraph (1)(A), by inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific uses identified in the application" after "health or the environment";

(B) in paragraph (2), by striking "data" each place it appears and inserting "information"; and

(C) in paragraph (4), by striking ". A rule promulgated" and all that follows through "section 6(c)" and inserting ", ~~without consideration of costs or other nonrisk factors,~~ including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use"; and

(9) by amending subsection (i) to read as follows:

"(i) DEFINITIONS.—(1) For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.

"(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.

"(3) For purposes of this section, the term 'applicable review period' means the period starting on the date the

Commented [GB8]: The striking of this language changes the relationship between 5(a) and 5(h) in current TSCA. Under current TSCA, this exemption (5h4) applies the same standard as the standard of review under (a), the logic being that EPA can exempt from new chemical review chemicals that it can determine upfront will meet the applicable standard. Since the review standard under the amended section 5(a) would be without consideration of cost or other nonrisk factors, it's not clear why the standard to be excused from review would not include the same language about cost and nonrisk factors. (We had made a similar comment on SLC about the absence of the "cost and other nonrisk" language in (h)(1)(A), lines 1-6 at the top of this page).

Administrator receives a notice under subsection (a)(1) and ending on the date the Administrator makes a determination under subsection (a)(3)(A), as extended pursuant to subsection (c) or (e)(1)(A).".

Commented [GB9]: This formulation seems to change (or at least confuses) the operation of the applicable review period from SLC. Under SLC, the period was a defined period of time: the 90 days given under (a), plus any extensions under b, c, or e. This HLC formulation appears to say that the period doesn't end until EPA makes the a3A determination. Note that neither this draft nor the SLC draft actually requires EPA ever to make the a3A determination (and this draft makes it seem even more discretionary, per the comment above). Maybe the intent is that the applicable period end following any extensions under c or e1A with or without a determination, but it doesn't really say that.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/23/2016 6:57:37 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request - Section 14

Michal – got it – checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 23, 2016 2:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request Section 14

Question - on the list in 14(b) of information generally protected from disclosure - are any of the items on the list items that EPA would currently not consider as CBI (unless it was publicly available etc)?

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 5:43:14 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal, we can do 3pm – ok? Can call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy. Thanks, Sven

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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 02, 2016 12:28 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Adding Adrian and Jonathan

There is ZERO interest in preserving the problem you're describing below. We are attempting to eliminate that problem. We have text we did not have when I first sent the question in that I am pasting excerpts of below so you can understand what we are thinking about. We'd like to schedule a call with you guys this afternoon between 1:30-4:30 (perhaps with other folks as well) so we can resolve this. Does that work?

Michal

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) Not later than 1 year after enactment, the Administrator shall establish, by rule, a process to conduct risk evaluations in order to determine, without consideration of costs or other non-risk factors, whether a high-priority chemical substance presents an unreasonable risk of injury to health or the environment from exposure to the chemical substance under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator.

(B) The Administrator shall conduct and publish a risk evaluation, in accordance with the rule promulgated under subparagraph (A), for a chemical substance–
  (i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and
  (ii) subject to subparagraph (D), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (A), be subjected to a risk evaluation.

(C) The Administrator shall, as soon as practicable and not later than 6 months of each designation of a high priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible populations the Administrator expects to consider.

"(E) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

"(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible populations identified as relevant by the Administrator;
"(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use was considered, and the basis for that consideration;
"(iii) not consider information on cost and other factors not directly related to health or the environment;
"(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
"(v) describe the weight of the scientific evidence for the identified hazard and exposure.

c) PROMULGATION OF SUBSECTION (a) RULES.
(1) If, based on a risk evaluation conducted in accordance with the rule promulgated under subsection (b)(4)(A[MVL1]), the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, , the Administrator—
(A) shall propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 12:09 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal,
This responds to your TA request on risk evaluations and unreasonable risk. Please let me know if any additional questions. Thanks,
Sven

Although there is too little detail to evaluate definitively, we have significant concerns with this proposed construct.

As you've described it, all risk management rules would still be subject to the current TSCA unreasonable risk standard, and EPA would still be limited by the same cost-benefit balancing analyses that have prevented effective action on chemicals in the past.

We also don't see the value in requiring EPA to issue a rule regarding risk evaluation with a preordained outcome: don't consider cost or other non-risk factors. This process will consume a significant amount of EPA time and resources, and delay the business of evaluating chemicals and protecting against identified risks. If Congress wants to preclude EPA from considering such factors in this context, the far more direct way to do so is by statutory directive.

Finally, if EPA is required to act by rule, commenters (and litigants) will likely argue that Congress must have intended EPA to have some discretion in the rulemaking, and will likely point to the authority to consider cost

as part of the risk management rulemaking to argue that EPA should be able to factor cost in some fashion into the underlying safety standard. As such, this proposed approach seems likely to leave unsettled for a protracted period of time the most significant TSCA policy shift made in both bills.

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 01, 2016 4:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 6 - quick unreasonable risk q

Here is a construct being discussed:

1) epa promulgates a rule for how risk evaluations are supposed to be conducted - study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors - the unreasonable risk "fix" is made in the rule itself.

2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 12:10:09 AM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Sen. Markey TSCA TA on house section 14 (4-22)
Attachments: Markey.TSCA TA.House Section 14 (4-22).docx; ATT00001.htm

Michal,
The attached TA responds to the request on house section 14 (4-22).

Please note that we are making comments only on changes. This section, for example, still contains the troubling "mixed information" section that we commented on recently. We have not commented again on that, but it demonstrates why we want to be sure that this TA is not interpreted as comprehensive comments on these documents.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

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This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

RLSO comparison of HLC 4.18 to 4.22

[DISCUSSION DRAFT]

SEC. 111. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) IN GENERAL.—Except as provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (c) are met.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

"(b) INFORMATION NOT PROTECTED FROM DISCLOSURE.—

@the relationship among these paragraphs is not entirely clear?

"(1) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Subsection (a) does not prohibit the disclosure of information that is not

Commented [GB1]: Agree – (b)(1) makes relationship confusing.

protected from disclosure under this section on the basis that such information contains information described in subsection (a), subject to the condition that the Administrator shall protect from disclosure the information described in subsection (a) in disclosing the information that is not protected from disclosure.

"(2) ~~[DATA]~~ INFORMATION FROM HEALTH AND SAFETY STUDIES.—~~[Subject to paragraph (1),]~~ subsection (a) does not prohibit the ~~disclosure of~~ disclosure of—

"(A) any health and safety study which is submitted under this Act with respect to—

"(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or

"(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5; and

"(B) any ~~[data]~~ information reported to, or ~~otherwise~~ otherwise obtained by, the Administrator from a ~~[~~health

and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the ~~release~~ / ~~disclosure~~ of any ~~data~~ which information, including formulas (including molecular structures) of a chemical substance or mixture, that discloses processes used in the manufacturing or processing of a chemical ~~substance~~ substance or mixture or, in the case of a mixture, the ~~release of data disclosing the~~ portion of the ~~mixture~~ mixture comprised by any of the chemical substances in the mixture.

~~the mixture. this is copied exactly from existing law. should 'data' be updated to 'information' and 'release' be changed to 'disclosure' to conform with the rest of the bill~~

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—~~Subject to paragraph (1),~~ ~~subsection~~ Subsection (a) does not ~~prohibit~~ prohibit the disclosure of—

"(A) a risk evaluation published under section 6~~(b)~~;

"(B) any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific ag-

Commented [GB2]: One way or another, be consistent.

Commented [GB3]: This could be read to suggest that formulas always disclose process information and are therefore always withholdable. If that is not the intent, this could be revised as follows: "This paragraph does not authorize the [release][disclosure] of any information that discloses processes used in the manufacturing or processing of a chemical substance or mixture (including formulas (including molecular structures) that disclose such processes). . . ."

gregated volumes would reveal confidential information, expressed in ranges; or

"(C) a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or

industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) BANS AND PHASE-OUTS.—

"(A) IN GENERAL.—If the Administrator promulgates a rule pursuant to section 6(a) that establishes a complete or partial ban or ~~phase-out with respect to a condition of use~~phase-out of a chemical substance or mixture, the protection from disclosure of any informa~~information~~tion under this section with respect to the chemical substance or mixture shall be presumed to no longer apply, subject to subsection (g)(1)(E) and subparagraphs (B) and (C) of this paragraph.

"(B) LIMITATIONS.—

"(i) CRITICAL USE.—In the case of a chemical substance or mixture for which a specific condition of use is subject to ~~a~~an exemption pursuant to section 6(~~)~~ ~~a 'critical use' exemption; need to check this ref~~

~~graph~~(g), if the Administrator establishes a ban or phase-out described in ~~subpara-~~ graph subparagraph (A) with ~~respect~~ re-spect to the chemical substance or mixture, the presumption against protection under ~~such subpara-~~ graph subparagraph shall only apply to ~~information~~ in-formation that relates solely to any ~~conditions~~ condi-

tions of use of the chemical substance or mixture to which the exemption does not apply.

"(ii) EXPORT.—In the case of a chemical substance or mixture for which there is manufacture, processing, or distribution in commerce that meets the conditions of section 12(a)(1), if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to ~~any~~any other ~~manufacturing~~manufacture, processing, or distribution in commerce~~,~~ ~~*is this correct? or should it be 'any condition of use other than such manufacture, processing, or distribution in commerce'?*~~ of the chemical substance or mixture, ~~un~~unless

less the Administrator makes the determination in section 12(a)(2).

"(iii) PARTIAL BANS AND PHASE-OUTS.—In the case of a chemical substance or mixture for which the Administrator establishes a partial ban or phase-out described in subparagraph (A) with respect to a specific condition of use of the chemical substance or mixture, the presumption pre-

Commented [GB4]: This suggests that this clause addresses partial bans for specific uses – ie, the whole use is not banned. Presumably the intent is for the clause to address bans for specific uses (which are partial bans of the chemical). If that's the intent, suggest dropping "partial" here.

sumption against protection under such ~~subpara-~~ ~~graph~~subparagraph shall only apply to ~~information~~information that relates solely to the condition of use of the chemical substance or mixture for which the ban or phase-out is ~~established~~established.

"(C) REQUEST FOR NONDISCLOSURE.—

"(i) IN GENERAL.—A manufacturer or processor of a chemical substance or mixture subject to a ban or phase-out described in this paragraph may submit to the Administrator, within 30 days of receiving a notification under subsection (g)(2)(A), a request, including documentation supporting such request, that some or all of the information to which the notice applies should not be disclosed or that its

disclosure should be delayed, and the Administrator shall review the request under subsection (g)(1)(E).

"(ii) EFFECT OF NO REQUEST OR DENIAL.—If no request for nondisclosure or delay is submitted to the Administrator under this subparagraph, or the Administrator denies such a request under sub-

section (g)(1)(A), the Administrator shall promptly make the information public shall not be protected from disclosure under this section.

"(5) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information ~~reported~~ reported to or otherwise obtained by the Administrator under this ~~Act (title)~~ Act that is not protected from disclosure under this subsection, the Administrator may not deny the ~~request~~ request on the basis of section 552(b)(4) of title 5, United States Code.

"(c) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect from disclosure any information that person submits under this ~~Act (title)~~ (in Act (including infor~~cluding information~~mation described in paragraph (2))

Commented [SD5]: Change from Senate version. Would make information nonconfidential without requiring that EPA make it public immediatelty.

shall assert to the Administrator a claim for protection from disclosure concurrent with ~~sub-~~ ~~missions~~submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has ~~promul-~~ ~~gated~~promulgated or may promulgate pursuant to this ~~title.~~ ~~title.~~

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) ADDITIONAL REQUIREMENTS FOR CLAIMS REGARDING CHEMICAL IDENTITY IN-

FORMATION.—In the case of a claim under subparagraph (A) for protection from disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall—

"(i) ~~the~~ be consistent with guidance~~, developed~~

~~[see questions below regarding guidance]~~

~~issued~~oped by the Administrator under paragraph (4)(A); and

"(ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are claimed as confidential; and

"(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

"(2) INFORMATION GENERALLY NOT SUBJECT TO SUBSTANTIATION REQUIREMENTS.—The following ~~information as identified by the Administ~~information shall not be subject to substan~~rator,~~

~~[this would clarify that the Administrator~~

~~could ask for information if needed to prove that something falls into one of these categories, as discussed; shall not be subject to substantiation requirements~~ substantiation requirements under paragraph (3):

"(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(B) Marketing and sales information.

"(C) Information identifying a supplier or customer.

"(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

"(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

"(F) Specific production or import volumes of the manufacturer or processor.

Commented [GB6]: This is harmless but adds nothing, because anyone producing or importing a chemical will be a manufacturer.

"(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the ~~chemical~~ chemical substance, including the chemical name, ~~molec-~~ular molecular formula, Chemical Abstracts Service ~~num-~~ber, number, and other information that would identify

the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 5.

"(3) SUBSTANTIATION REQUIREMENTS.—Except for information described in paragraph (2), a person asserting a claim to protect information from disclosure under this section ~~shall~~ shall substantiate the claim, in accordance with such rules as the Adminis-

trator has promulgated, and or may promulgate pursuant consistent with guidance developed, ¿ ~~this seems weird from an APA perspective if a person is statutorily required to follow the guidance, it would probably end up being treated the same as a rule from a procedural standpoint, so to the extent that letting the Administrator do some things through guidance instead of a rule is intended to obviate the need for full rulemaking procedures,~~ this ~~might negate that if that is a problem, might be better to say something more general here, like 'shall substantiate the claim in accordance with such requirements as the Administrator may establish'~~ ¿ by the Administrator section.

"(4) GUIDANCE.—The Administrator shall develop ~~guidance ¿ so, just checking, is this intended to be true~~ guidance, ~~or is it meant to be required to be followed? (1)(C) and (d)(4), (5), and (6) make it sound like they are requirements~~ ¿ regarding—

Commented [GB7]: This has been changed so that the substantiation guidance EPA develops under paragraph (4) is no longer binding – substantiation must be in accordance with any EPA rules, but not consistent with guidance.

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection from disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (d).

"(5) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B), and any information required to substantiate a claim submitted pursuant to paragraph (3), are true and correct.

"(d) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Information described in subsection (a)—

"(1) shall be disclosed to an officer or employee of the United States—

"(A) in connection with the official duties of that person under any Federal law for the ~~protection~~ protection of health or the environment; or

"(B) for a specific Federal law ~~enforcement purenforce~~-

~~pose~~ment purpose;

"(2) shall be disclosed to a contractor of the United States and employees of that contractor ~~if~~—

Commented [GB8]: These change explicitly limit the disclosure to federal employees to the situation where it's required to carry out *Federal* law, but that was probably implied anyway.

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines, ~~without consideration of costs or other~~that disclosure is necessary to protect ~~non-risk factors, that disclosure is necessary to protect~~ health or the environment against an ~~unreasonable~~unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use;

"(4) shall be disclosed to a State, political subdivision of a State, or tribal government, on written request, for the purpose of administration or enforcement of a law, if such entity has 1 or more applicable agreements with the Administrator that are consistent with the ~~guidance~~guidance developed under sub-

Commented [GB9]: Need to drop this comma

Commented [GB10]: Move seems ok but be consistent – it appears after "determines" in other formulations in the bill (or at least it did – maybe those have all been changed).

section (c)(4)(B) and ensure that the entity will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the proce-

dures used by the Administrator to safeguard the information;

"(5) shall be disclosed to a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation if such person provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement are consistent with the ~~guidguid~~ance; developed under subsection (c)(4)(B);

Commented [GB11]: Note that this guidance remains "enforceable", whereas the substantiation guidance now is not.

"(B) the statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure

to the chemical substance or mixture concerned has occurred; and

"(C) the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person who has a claim under this section with respect to the information, ~~except~~except that nothing in this title prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law~~; (this is a pretty broad statement. why is it being placed here, and not somewhere more general in the section?)~~;

law;

~~18~~19 "(6) shall be disclosed in the event of an emergency~~.~~ to a treating or responding physician, nurse, ~~agent of a poi-~~

~~19~~21 ~~son~~poison control center, public health or ~~environmental~~environmental official of a State, political subdivision ~~of a State, or~~

tribal government, or first responder ~~(including any~~

individual duly authorized by a Federal Fed-
eral agency,
State, political subdivision of a State, or

tribal government who is trained in urgent medical care or other emergency procedures, including a police offi-

service officer, firefighter, or emergency medical techniciantechnician) if such person requests the information, subjectsubject to the conditions that such person shall—

"(A) have a reasonable basis to suspect that—

"(i) a medical, public health, or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

"(B) if requested by a person who has a claim with respect to the information under this section—

"(i) provide a written statement of need and agree to sign a confidentiality

agreement, as described in paragraph (5); and

"(ii) submit to the person who has the claim or to the Administrator, or both; and

such statement of need and confidentiality agreement as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the ~~maximum~~ extent practicable without impair:

~~without impairing~~ the proceeding; ~~or~~ and;

"(8) shall be disclosed if the information is required to be ~~disclosed or otherwise~~ made public under any other provision of Federal law.

"(e) DURATION OF PROTECTION FROM DISCLOSURE.—

"(1) IN GENERAL.—~~Subject to paragraph (2),~~ ~~the~~The Administrator shall protect from disclosure ~~information~~information described in ~~subsection~~subsection (a)—

Commented [SD12]: Language does not reflect suggested changes from the Senate.

"(A) in the case of information described in subsection (c)(2), until such time as—

"(i) the person that asserted the claim notifies the Administrator that the person

is withdrawing the claim, in which case the

Administrator information shall promptly make the in not be protected from formation available to the public disclosure under this section; or

"(ii) the Administrator becomes becomes aware that the information does not qualify qualify for protection from disclosure under this section; should this have to go through the review process in paragraph (2) first? tion, in which case the Administrator shall take any actions required under subsection (f); and should this instead be that the Administrator reviews the claim under subsections (f) and; what would happen under (f)? (f) appears to not apply to (c)(2) information strike?; (2) and decides it no longer qualifies? if not, how does a review there interact with this?;

(g); and

"(B) subject to paragraph (2), subsection (f)(3), and section 8(b); link is needed to prevent conflicting deadlines; in the case of information) infor-

Commented [GB13]: (f) does apply to c2 information

Commented [GB14]: "Subject to paragraph (2) was stricken in (A) and should be stricken here, along with the other citations – we don't see how they are needed.

~~mation~~ other than

information described in ~~subsection (c)(2) sub-~~ section (c)(2)—

"(i) for a period of 10 years ~~of from~~ from the ~~date on which~~; ~~or~~

"(I) ~~the~~ the person ~~submits~~ asserts the ~~in-~~ claim

~~formation~~ with respect to the ~~Administrator~~ information to the Administrator; or

~~"(II) the Administrator makes a determination that the claim continues to meet the relevant requirements of this section after requiring a person to~~

Commented [SD15]: should be "submitted to the Administrator".

~~reassert and substantiate or resubstan-~~

~~tiate a claim under paragraph (2)(C); or~~

"(ii) ~~if~~ if applicable before the ~~expiration~~ expiration of such 10-year period ~~or any extension,~~ since this is ~~granted under subparagraph (B), an 'or' list and (I) has a set period, need a~~ rule to decide which clause applies; until such time as—

Commented [GB16]: Not sure what point is being made

"(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the ~~Administrator~~information shall ~~promptly make the information available to the public~~not be protected from disclosure under this section; or

"(II) the Administrator ~~becomes~~becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under ~~subsection~~subsections (f) and (g). ~~as above regarding interaction with paragraph (2).~~

"(2) EXTENSIONS.—

"(A) IN GENERAL.—In the case of information other than information described in subsection (c)(2), not later than the date that is 60 days before the expiration of the period de-

Commented [SD17]: change in Senate version. Means that EPA would not necessarily have to immediately make the information public.

scribed in paragraph (1)(B)(i), the Administrator Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(B) REQUEST.—

"(i) IN GENERAL.—Not later than the date that is 30 days before the expiration

of the period described in paragraph (1)(B)(i), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (c)(3), the need to extend the period.

"(ii) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in paragraph (1)(B)~~, the~~(i), the Administrator shall, in accordance with subsection (g)(1)—

"(I) review the request submitted under clause (i);

"(II) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant requirements of this section; and

"(III)(aa) grant an extension of 10 years; or

"(bb) deny the request.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under this paragraph, if

the Administrator determines that the relevant request under subparagraph (B)(i)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(f) REVIEW AND RESUBSTANTIATION.—

[is anything in this subsection intended to apply to (c)(2) information?]

Commented [GB18]: It applies equally to (c)(2) information and non-(c)(2) information. What about the text would suggest otherwise?

"(1) DISCRETION OF ADMINISTRATOR.—The Administrator may ~~require~~, under this subsection, ~~what does this add? okay to require strike?~~ any person that has claimed protection for information from ~~dis~~disclosure ~~closure~~ under this section, whether before, on, or after the date of enactment of the Frank R. ~~Lauten~~Lautenberg ~~berg~~ Chemical Safety for the 21st Century Act, to ~~re~~ ~~reasser~~assert and substantiate or resubstantiate the claim in accordance with ~~subsection~~ subsection (c) *[/ this section?]*

[see below]—

"(A) after the chemical substance is ~~d~~designated as a high-priority substance under section 6(b)*[; need to check this reference]*;

"(B) for any ~~chemical~~chemical substance designated as an ~~inactive~~active substance under section 8(b)(~~4~~)(A)(~~5~~)(B)(iii)~~; need to check this reference~~); or

"(C) if the Administrator determines that disclosure of certain information currently protected from disclosure would be important to assist the Administrator in conducting risk evaluations or promulgating rules under section 6.

"(2) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information from disclosure under this section and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to reassert and substantiate or resubstantiate the claim in accordance with ~~this~~ section [subsection (c)? see above?]

Commented [GB19]: Agree that these two provisions should be consistent. "This section" may be better.

"(A) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(B) if the Administrator has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section; or

"(C) for any chemical substance the Administrator determines in accordance with ~~section 6(under?; section 6~~(b)(4)(A)~~; need to check this reference~~) presents an ~~unreasonable~~ unreasonable risk of injury to health or the ~~environment~~ environment.

"(3) PERIOD OF PROTECTION.—If the ~~Admin~~Administrator requires a person to reassert and ~~substan~~substantiate ~~tiate~~ or resubstantiate a claim under this ~~paragraph~~, subsection, and determines that the claim continues to meet the relevant requirements of this section, the ~~Administrator~~ Administrator shall protect the information subject to the claim from disclosure for a period of 10 years from the date of such determination, subject to any subsequent requirement by the Administrator under this paragraph. ~~depending on answers in (1)(A), this may be entirely taken care of there. if so, strike this subparagraph~~ subsection.

"(g) DUTIES OF ADMINISTRATOR.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except for claims regarding information described in subsection

(c)(2), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (c), and not later than 30 days after the receipt of a request for extension of a claim under subsection (e) or a request under subsection (b)(4)(D), review

and approve, approve in part and deny in part, or deny the claim or request. ~~@given what's in (C) and (D), what does this subparagraph actually do?@~~

"(B) REASONS FOR DENIAL.—If the Administrator denies or denies in part a claim or request under subparagraph (A) the Administrator shall provide to the person that asserted the claim or submitted the request a written statement of the reasons for the denial or denial in part of the claim or request.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims with respect to information described in subsection (c)(2)(G), review all claims or requests under this section for the protection from disclosure of the specific chemical identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection from disclosure under this section.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection from disclosure or extension under this section shall

not have the effect of denying or eliminating a claim or request for protection from disclosure.

"(E) DETERMINATION OF REQUESTS UNDER SUBSECTION (b)(4)(C).—With respect to a request submitted under subsection (b)(4)(C), the Administrator shall, with the objective of ensuring that information relevant to the protection of health and the environment is disclosed to the ~~o~~maximum extent practicable, determine ~~d~~determine whether the documentation provided by the ~~person~~per- ~~s~~son rebuts what shall be the ~~pre-~~ ~~sumption~~presumption of the Administrator that the public interest in the ~~d~~disclosure of the information ~~out-~~ ~~weighs~~ outweighs the ~~p~~public or proprietary interest in maintaining the ~~p~~protection for all or a portion of the ~~information~~informa- ~~t~~tion that the person has re-

~~quested~~requested not be ~~disclosed~~dis-
~~closed~~ or for which disclosure
be delayed.
"(2) NOTIFICATION.—
"(A) IN GENERAL.—Except as provided in
subparagraph (B) and subsections (b), (d), and
(e), if the Administrator denies or denies in
part a claim or request under paragraph (1),
concludes, in accordance with this section, that
the information does not qualify ~~or no longer~~for
protection
~~qualifies? *redundant, okay to strike?*? for pro-~~
~~tection~~ from disclosure, intends to disclose ~~in-~~
information
~~formation~~

pursuant to subsection (d), or ~~pro-~~ promulgates ~~mulgates~~ a rule under section 6(a) establishing a ban or phase-out with respect to a chemical substance or mixture, the Administrator shall notify, in writing, the person that asserted the claim or submitted the request of the intent of the ~~Administrator~~Administrator to disclose the information~~, or not~~ protect the information from disclosure under this section. The notice shall be furnished by ~~personally~~ certified mail (return receipt requested), by ~~personal~~ sonal delivery, or by ~~any~~ other ~~[anyway]~~ means that allows verification of the fact and date of receipt.

"(B) DISCLOSURE OF INFORMATION.—Except as provided in subparagraph (C), the Administrator shall not disclose information under

this subsection until the date that is 30 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A).

"(C) EXCEPTIONS.—

"(i) FIFTEEN DAY NOTIFICATION.—For information the Administrator intends to disclose under subsections (d)(3), (d)(4), (d)(5), and (i), the Administrator shall not disclose the information until the date that

is 15 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A), except that, with respect to information to be disclosed under subsection (d)(3), if the Administrator determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, ~~in which case no prior notifica~~notification shall be necessary.

~~tion shall be necessary.~~

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information the Administrator intends to disclose under paragraph (6) of subsection (d), the Administrator

shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of information under paragraphs (1), (2), (7), or (8) of subsection (d); or

"(II) for the disclosure of information for which—

"(aa) the Administrator has provided to the person that asserted the claim a notice under subsection (e)(2)(A); and

"(bb) such person does not submit to the Administrator a request under subsection (e)(2)(B) on or before the deadline established in subsection (e)(2)(B)(i).

"(D) APPEALS.—

"(i) ACTION TO RESTRAIN DISCLOSURE.—If a person receives a notification under this paragraph and believes the information is protected from disclosure

under this section, before the date on which the information is to be disclosed pursuant to subparagraph (B) or (C), the person may bring an action to restrain disclosure of the information in—

"(I) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(II) the United States District Court for the District of Columbia.

"(ii) NO DISCLOSURE.—

"(I) IN GENERAL.—The Administrator shall not disclose ~~any information~~ information that is the subject of an ~~appeal~~appeal under this paragraph before the date on which the applicable court rules on an action under clause (i).

"(II) EXCEPTION.—Subclause (I) shall not apply to disclosure of information described under subsections (d)(4) and (j).

"(3) REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention,

shall develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).

"(4) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical iden-

tity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by their unique ~~identifier~~identifiers, for which claims to protect the ~~specific~~specific chemical identity from disclosure have been ~~approved~~approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to a chemical substance included on the

list published under subparagraph (B) while the specific chemical identity of the chemical substance is protected from disclosure under this section

~~"(i) is made public; and; and~~

~~"(ii) seems to contradict the policy described in the meeting that not all nonconfidential information needs to affirmatively be made public, how does this subparagraph fit in to that policy?.~~

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of a specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the person who asserted the

claim, and for which the Administrator has used a unique identifier assigned under this paragraph to ~~identify~~protect the specific chemical iden-
tity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such infor-
mation to the ~~maximum~~ extent practicable.

"(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
SURE.—

"(1) INDIVIDUALS SUBJECT TO PENALTY.—

"(A) IN GENERAL.—Subject to subparagraph (C) and paragraph (2), an individual described in subparagraph (B) shall be ~~guilty of~~ a misdemeanor and, ~~Judiciary drafters suggest that this is unnecessary. strike~~, fined under title 18, United States Code, or ~~imprisoned for~~imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—An individual referred to in subparagraph (A) is an individual who—

"(i) pursuant to this section, obtained possession of, or has access to, information protected from disclosure under this section; and

"(ii) knowing that the information is protected from disclosure under this section, ~~willfully, Judiciary drafters note that this could be interpreted in this context as meaning either 'recklessly' or 'intentionally' if there is a preferred policy, better to replace with one of those terms, otherwise can leave up to the courts,~~ willfully discloses the information in

any manner to any per-

son person not entitled to receive that informa- tion information.

"(C) EXCEPTION.—This paragraph shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information ~~ob~~ob- tained under paragraph (5) or (6) of subsection (d)(2) to ~~the affected patient /~~ a patient treated by the medical ~~professional, or the legal rep~~profes- sional, or to a person authorized to make medical or health care decisions on behalf of such ~~a patient,~~ as ~~for example, if~~ the a patient ~~is a minor or incapacitated,~~ as ~~part of~~ needed ~~with respect to~~ for the diagnosis or treatment of the patient, ~~may the patient~~treat- ment of the patient ~~then disclose the information (for example, to an other doctor for a second opinion or to a spouse)? if so, need to include~~ment of the patient ~~in this~~. ~~exception, along with any limitations desired.~~

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, or making known of information reported to or otherwise ob-

Commented [SD20]: Senate version uses "legal guardian"; this version uses broader language.

tained by the Administrator under this Act. ~~Under any drafters note that it is unclear what this paragraph is intended to achieve.~~

"(i) APPLICABILITY.—

"(1) IN GENERAL.—Except as otherwise provided in this section, ~~@section~~section 8 ~~@need to check this reference~~, or any other ~~applicable~~applicable Federal law, the Administrator shall have no ~~authority—au-~~ thority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information reported to or

otherwise obtained by the Administrator under this Act prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or re-substantiation requirements ~~under this Act that~~, with respect to the protection of information described in subsection (a) under this Act that are more ~~extensive~~exten-sive than those required under this section.

"(2) ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or re-substantiation of, or approving, approving in part, or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century

Act. this may be taken care of elsewhere in the bill. if so, strike here.

Act.

"(j) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon writ-

1 ten request of any duly authorized committee of the Con-
2 gress, to such committee.".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 3:35:13 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Section 4(a)(1)

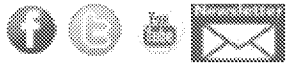
Got it - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 05, 2016 11:34 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Markey TSCA TA Request on Section 4(a)(1)

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 25, 2016 12:04 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA Request on Section 4(a)(1)

Michal – please see TA below responding to the request on section 4(a)(1). Please let me know if any questions. Thanks,
Sven

Question

In the list of items under senate 4(a)(1) - list of 4 conditions where there is testing allowed by order. In discussing a hybrid House/Senate concept, a question was raised about whether RULES could be required for some or all of the 4(1)(B) items rather than orders. Tell us of any downsides - argument is that epa is already writing a 6(a) rule that may include a restriction related to testing, and same w potentially 5(d). What we'd like is your assessment of scenarios in which a requirement to do rules rather than orders in 4(1)(B) would be a problem. It may be that all scenarios are problems - but it may also be that there are some scenarios where it would not be.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.
(a) TESTING REQUIREMENTS

(1) IN GENERAL. – The Administrator may, by rule, order, or consent agreement, require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary –
(A) to review a notice under section 5(d) or to perform a risk evaluation under section 6;
(B) to implement a requirement imposed in a rule, consent agreement or order issued under section 5(d) or under a rule promulgated under section 6(a);
(C) pursuant to section 12(a)(4); or
(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

EPA Response:
We have a number of concerns with the suggested removal of order authority from all or part of the Senate's Section 4(a)(1).

EPA's difficulty in requiring development of information on chemicals is a major problem under current law. There are two main issues. First, existing law requires EPA to make a risk or exposure finding in order to require testing under Section 4. When data on a chemical is lacking, it is very challenging for EPA to exercise its Section 4 authorities. Second, even if EPA is able to clear the initial Section 4 hurdle, it must then go through a lengthy rulemaking to require the testing and get the data - potentially a 3-5 year process. Continuation of the rulemaking requirement unnecessarily delays EPA from getting the information it needs to assess a chemical's safety, and would almost certainly prevent EPA from meeting statutory deadlines under the House and Senate bills for completing risk evaluations

With respect to the argument you described, it is hypothetically possible that EPA might promulgate a testing requirement concurrently with a section 6(a) or 5(d) rule. But it is also possible that the testing need will not become apparent until the restriction under 5 or 6 is already in place. If successful implementation of a protective requirement is dependent on information to be developed under Section 4, it is imperative that EPA have order authority to require that information in an expeditious manner.

The Administration's Principles very clearly call for EPA to be given "the necessary authority and tools…to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals." The recent Administration's views letter echos that sentiment, commending both the House and Senate for providing EPA with new order authority in Section 4. We'd underscore the importance of order authority again here.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 23, 2016 3:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 4

Sven

In the list of items under senate 4(a)(1) - list of 4 conditions where there is testing allowed by order. In discussing a hybrid House/Senate concept, a question was raised about whether RULES could be required for some or all of the 4(1)(B) items rather than orders. Tell us of any downsides - argument is that epa is already writing a 6(a) rule that may include a restriction related to testing, and same w potentially 5(d). What we'd like is your assessment of scenarios in which a requirement to do rules rather than orders in 4(1)(B) would be a problem. It may be that all scenarios are problems - but it may also be that there are some scenarios where it would not be.

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/28/2016 5:54:04 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on costs analysis

Michal – thanks for letting me know – will pass along. Please let me know if any additional questions. Best, Sven

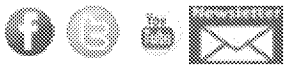
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 28, 2016 1:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on costs analysis

On the "category of articles" comment – I understood you guys perfectly and was fine with the House's proposed deletion. Others, however, ALSO understood the impact of the proposed deletion perfectly, and rejected the House proposal. ☺

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 28, 2016 6:36 AM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA request on costs analysis

Michal,
Resend with both documents attached. Please let me know if any questions. Thank,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Wednesday, April 27, 2016 9:04 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request on costs analysis

Michal,
This TA responds to the request on cost considerations.

In particular, there are three comments to point out. The most important is the comment on p. 49 [44] of the second document (RLSO of HLC 4 22), which addresses the cost analysis issue for alternatives we have discussed.

The other two are on p. 137 [124] of that document (addressing discrepancies in the drafting of section 21) and p. 8 of the first document (suggesting text to align the sec 5 review period with the obligation to respond to information submitted).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/11/2016 1:24:20 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on Chem ID

Michal- got it- thanks,
Sven

On Apr 11, 2016, at 9:23 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Getting back to this question from a different direction – your TA below says that there is a 3rd basis for withholding chemID from HS: "where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study."

We have the pre-NOC exclusion in current senate 14

> (i) <!--[if !supportLists]--><!--[endif]-->The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

I am wondering if "if the specific identity is not necessary to interpret the HS study" is something that I should be exploring in addition to the other ideas for inclusion alongside process and concentration/proportion. To that end, is there an easy way that you could provide me with some statistics/#s along the following lines (approximate #s ok)

1- <!--[if !supportLists]--><!--[endif]-->How many chemID CBI claims are there generally? Per year?
2- <!--[if !supportLists]--><!--[endif]-->How many chem IDs are withheld (both generally and per year) from HS studies because releasing would reveal
    a. <!--[if !supportLists]--><!--[endif]-->Process
    b. <!--[if !supportLists]--><!--[endif]-->Concentration/proportion
    c. <!--[if !supportLists]--><!--[endif]-->Pre-NOC AND info not necessary

If this is impossible to figure out in a quick timeframe let me know and maybe we can figure out some other way to answer my question, which is, generally, "what is the actual impact of adding the specific identity is not necessary to interpret the health and safety study" under this EPA's practice.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 09, 2016 12:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,
This TA responds to the request on chem ID.

Your two emails seem to be asking questions in different directions: the first seems to be asking whether another basis could be added for allowing the withholding of chem id *in health and safety studies* (presumably something industry would want), and the second seems to be asking the very different question of whether there should be more stringent expiration or voiding conditions for chem id *outside the context of health and safety studies* than for other CBI (presumably something the NGOs would want).

Re your first question: although the statute allows for withholding of chem ID (or other info) in health and safety studies only on two bases (reveals process information of proportions of a mixture), EPA regulations allow withholding of specific chem ID on a third basis: where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study. That kind of provision could be codified in the bill.

Re your second question: The idea sounds like a beefing up of sec 14(c)(3) of the Senate offer, which presumptively voids CBI claims for chem ID and other information elements following a ban of a chemical. The triggering event for that provision could be moved up to the finding of unreasonable risk.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 11:20:40 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on ChemID

As part of your thought process here, and perhaps as an alternative option, let's think about a way where if chemID is kept CBI it goes public if a) epa makes a section 6 or 7 unreasonable risk finding about it and b) it has to be re-substantiated every 5/10 years with reasonable potential of an unreasonable risk being one of the things EPA has to consider.

Michal Ilana Freedhoff, Ph.D.

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On Apr 9, 2016, at 5:40 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Good morning

We increasingly hear that "molecular structure" is a huge threshold issue for the House. It is for us too. I'm trying to learn more about the history here and also see if there exists middle ground - something akin to a 3rd condition for when chemID is withheld, like "keep molecular structures secret if X or Y, or unless X or Y". I'm not sure if a space like this exists for either side, but thought perhaps looking towards the recent decisions by EPA on why it did or did not release molecular structure could be useful.

Can you put together background materials or suggestions if you have any? Doesn't have to be before 1, but would be helpful if it was before 5 or 6 pm so I can review tonight as part of some of the other prep work I'm planning.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 9:34:34 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on nomenclature language
Attachments: Markey.TSCA TA.nomenclature with savings (4-20).docx

Michal,
The attached TA responds to the request on nomenclature language (4-20).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.
''(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:
Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

''(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.'';

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

.—

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all chemical substances described by the following category listings, when manufactured as described in such appendix, as being included on the list published under paragraph (1) under the

Commented [A1]: EPA TA: The language in (A)(iii) is fine. It simply provides that whether or not a particular chemical substance qualifies as being listed on the inventory under one of these inventory listings depends on how EPA defined the inventory listings at the time EPA established the inventory. This text doesn't resolve one way or the other any dispute about how to construe any of these inventory listings, and it is clear about which inventory listings it is talking about.

Note though that it would be helpful to clarify your drafting intent in the final legislative history. The Senate conference report contains some confusing statements about continuing the current policy of "not requiring notification for variations in . . . mixtures, which (if unaddressed) could influence subsequent interpretation of this passage.

Chemical Abstracts Service numbers for the respective categories:

"(I) Cement, Portland, chemicals, CAS No. 65997–15–1.

"(II) Cement, alumina, chemicals, CAS No. 65997–16–2.

"(III) Glass, oxide, chemicals, CAS No. 65997–17–3.

"(IV) Frits, chemicals, CAS No. 65997–18–4.

"(V) Steel manufacture, chemicals, CAS No. 65997–19–5.

"(VI) Ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) maintain the nomenclature conventions for chemical substances; and

"(II) develop new guidance that—

Commented [A2]: EPA TA: Overall, (B) remains problematic. As described below, the savings clause intended to address (B) doesn't currently guard against the problems with (B), and it introduces other problems.

Commented [A3]: EPA TA: This provision requires EPA to "maintain the nomenclature conventions for chemical substances" with no guidance as to what conventions are referred to. The HLC draft suggests that EPA must maintain any nomenclature conventions, whether or not they have been recognized or are considered valid by EPA.

We suggest clarifying which nomenclature conventions you are referring to.

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of identifying ~~determining whether~~ a chemical substance that is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For a chemical substance determined by the Administrator to appear multiple times on the list in paragraph (1) under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(C) RELATIONSHIP TO SECTION 5.—

"(i) CHEMICAL SUBSTANCES DESCRIBED BY CATEGORIES.—Notwithstanding subparagraph (A), a chemical substance that is described by a category listed in subparagraph (A)(iii) shall be subject to section 5 if the chemical sub-

Commented [A4]: EPA TA:

(aa) is limited in scope to chemical substances that are already on the TSCA Inventory.

If your intent is to give (bb) the same scope, it should be conformed to (aa). Under current drafting it seems to be suggesting that different naming conventions could be a pathway for giving a *de facto* Inventory listing to a chemical substance that is not currently listed on the Inventory.

The C(ii) savings clause won't guard against this issue, if (B) isn't fixed, because anyone who thinks that they have a *de facto* Inventory listing under (bb) will simply argue that because they are *de facto* listed on the Inventory, due to (bb), the (C)(ii) savings clause doesn't apply to them.

Also, as noted above, a savings clause that merely specifies that a chemical is "subject to section 5," doesn't pin down whether or not the chemical substance is to be treated as a new chemical substance.

Commented [A5]: EPA TA: If the intent is to provide that such chemicals are considered to be new chemical substances (and thus subject to PMN review), then that would be better stated directly. Simply stating that a chemical is "subject to section 5" doesn't actually establish whether the chemical is a new chemical substance for which a PMN is required. All chemical substances (new and existing) are subject to section 5 because they can be SNUR'd.

stance is not ~~included as an individual chemical substance~~ individually listed on the list published under paragraph (1) as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) CHEMICAL SUBSTANCES GROUPED BY CAS NUMBER.—Notwithstanding subparagraph (B), a chemical substance that is not included as an individual chemical substance on the list published under paragraph (1) as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act shall be subject to section 5.".

◇

Commented [A6]: EPA TA: If the intent is to refer to a chemical substance not individually listed on the inventory, it would be better to say that. A chemical could be said to be included as an individual chemical if it is captured within a broader listing, and yet that is the scenario that you seem to want to exclude here.

Commented [A7]: EPA TA: This breadth of this provision is sweeping: It covers any individual chemical substance that may be present as a constituent of an existing UVCB chemical substance.

This would be important if "shall be subject to section 5" is modified to clearly specify that a new chemical notice is required. In that case, all of the unknown ingredients of all the various UVCBs being manufactured pursuant to UVCB Inventory listings would all suddenly need PMNs if the don't already have individual listings. This would largely undercut the point of having UVCB chemical substances in the first place.

Commented [A8]: EPA TA: As noted above, this doesn't actually clarify whether the chemical is a new chemical or not.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2016 10:59:39 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it-checking along with the last one. Thanks,
Sven

On Mar 16, 2016, at 6:46 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

<!--[if !supportAnnotations]--> <!--[endif]-->
Does this work for 14(c)(3)(B)

(B) EXCEPTIONS FROM PRESUMPTION
(i) Paragraph (3)(A) shall not apply to any condition of use of a chemical substance for which an exemption under section 6(g) has been granted;
(ii) For a ban or phase-out of a chemical substance that is not established for all conditions of use of the chemical substance, paragraph (3)(A) shall apply only to information about the chemical substance that relates solely to the conditions of use for which the ban or phase-out is established ;
(iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured, processed and distributed solely for export if EPA determines that section 12(a)(1) shall not apply to the chemical substance in accordance with section 12(a)(2). <!--[if !supportAnnotations]--><!--[endif]--> ; and
(iv) Paragraph (3)(A) shall apply to a chemical substance that is subject to a phase out at such time as the phase out is fully implemented.

Michal Ilana Freedhoff, Ph.D.
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Office of Senator Edward J. Markey
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Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 4:43 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 1:16 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

(c) Information Not Protected From Disclosure.—
(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:
(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
(i) IN GENERAL.—Subject to clause (ii)—
(I) any health and safety study that is submitted under this Act with respect to—
(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or
(bb) any chemical substance or mixture for which—
(AA) testing is required under section 4; or
(BB) a notification is required under section 5; or
(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).
(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—
(I) a process used in the manufacturing or processing of a chemical substance or mixture; or
(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.
(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:
(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).
(ii) A safety assessment developed, or a safety determination made, under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
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Office of Senator Edward J. Markey
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202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 1:13 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,
This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 10:32 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<!--[if !supportAnnotations]-->

<!--[endif]-->

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 9:03:05 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Markey TSCA TA Request on partial REs

Michal – got it. Will circulate for response. In the queue between 5 and 26, unless would derail 26. Thanks, Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 19, 2016 5:01 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: partial REs

For after you finish with 5, and only if it is not going to delay you sending 26 (it is a 26 issue).

I am wondering if this is why House keeps baking least burdensome back into the partial RE language in 26. I'm not at all interested in the suggested CSAC approach as it won't exist in the right timeframe. I'd be interested in your thoughts on the IQA idea, but am thinking it probably makes sense to cite to the science language in 26 in the partial RE section and be done. I'd be interested in your thoughts

michal

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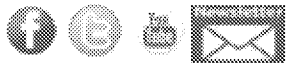

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 5:29:07 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal – got it – checking on availability. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 02, 2016 12:28 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Adding Adrian and Jonathan

There is ZERO interest in preserving the problem you're describing below. We are attempting to eliminate that problem. We have text we did not have when I first sent the question in that I am pasting excerpts of below so you can understand what we are thinking about. We'd like to schedule a call with you guys this afternoon between 1:30-4:30 (perhaps with other folks as well) so we can resolve this. Does that work?

Michal

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) Not later than 1 year after enactment, the Administrator shall establish, by rule, a process to conduct risk evaluations in order to determine, without consideration of costs or other non-risk factors, whether a high-priority chemical substance presents an unreasonable risk of injury to health or the environment from exposure to the chemical substance under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator.

(B) The Administrator shall conduct and publish a risk evaluation, in accordance with the rule promulgated under subparagraph (A), for a chemical substance–
  (i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and
  (ii) subject to subparagraph (D), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (A), be subjected to a risk evaluation.

(C) The Administrator shall, as soon as practicable and not later than 6 months of each designation of a high priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible populations the Administrator expects to consider.

"(E) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

"(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible populations identified as relevant by the Administrator;
"(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use was considered, and the basis for that consideration;
"(iii) not consider information on cost and other factors not directly related to health or the environment;
"(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
"(v) describe the weight of the scientific evidence for the identified hazard and exposure.

c) PROMULGATION OF SUBSECTION (a) RULES.
(1) If, based on a risk evaluation conducted in accordance with the rule promulgated under subsection (b)(4)(A[MVL1]), the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, , the Administrator—
(A) shall propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

Michal Ilana Freedhoff, Ph.D.
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202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 12:09 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal,
This responds to your TA request on risk evaluations and unreasonable risk. Please let me know if any additional questions. Thanks,
Sven

Although there is too little detail to evaluate definitively, we have significant concerns with this proposed construct.

As you've described it, all risk management rules would still be subject to the current TSCA unreasonable risk standard, and EPA would still be limited by the same cost-benefit balancing analyses that have prevented effective action on chemicals in the past.

We also don't see the value in requiring EPA to issue a rule regarding risk evaluation with a preordained outcome: don't consider cost or other non-risk factors. This process will consume a significant amount of EPA time and resources, and delay the business of evaluating chemicals and protecting against identified risks. If Congress wants to preclude EPA from considering such factors in this context, the far more direct way to do so is by statutory directive.

Finally, if EPA is required to act by rule, commenters (and litigants) will likely argue that Congress must have intended EPA to have some discretion in the rulemaking, and will likely point to the authority to consider cost

as part of the risk management rulemaking to argue that EPA should be able to factor cost in some fashion into the underlying safety standard. As such, this proposed approach seems likely to leave unsettled for a protracted period of time the most significant TSCA policy shift made in both bills.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 01, 2016 4:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 6 - quick unreasonable risk q

Here is a construct being discussed:

1) epa promulgates a rule for how risk evaluations are supposed to be conducted - study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors - the unreasonable risk "fix" is made in the rule itself.

2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 4:42:25 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on Jackie's 6

Got it- thanks

On Apr 15, 2016, at 12:41 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Also pls look at her new "low hazard" thing in 6.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, April 15, 2016 12:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on Jackie's 6

Michal,
This TA responds to the request on Jackie's draft section 6., re: **the alternatives analysis language, p11 , line 5.**

This language is consistent with the type of analysis that EPA would already do in the absence of statutory mandate, and we do not see a significant issue with it. That being said, one way to soften the requirement would be to replace "determine" (p.11, line 10) with "consider." See text below. Doing so would reduce opportunities for litigation on the sufficiency of EPA's "determination" – a separate administrative action that can be challenged.

‘‘(C) based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, ~~determine~~ consider whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 15, 2016 at 10:29:08 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Jackie's 6

Also pls see alternatives analysis p 11 line 5. We need to include something like this. Need this back asap. I was hoping to limit this language to bans and phaseouts but in the past you've said you would do this analysis anyway and want your take on this.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Friday, April 15, 2016 10:23 AM

To: Freedhoff, Michal (Markey)

Subject: Re: Jackie's 6

Got it - checking

On Apr 15, 2016, at 10:22 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

On section 6 pls esp look at p 10 lines 14 and on. And rank on the chart? Asap would be good.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<Jackie section 6.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 10:30:07 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal - no issues with the edits. Please let me know if any additional questions. Thanks,
Sven
Sven-Erik Kaiser

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Washington, DC 20460
202-566-2753

On Apr 23, 2016, at 6:13 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Ty – any issues w these edits?

- <!--[if !supportLists]--><!--[endif]-->Page 150 line 19 – Insert "the date on which" before "an order"
- <!--[if !supportLists]--><!--[endif]-->Page 150 line 19 – Insert "is issued" after "an order"

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202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 6:12 PM
To: Freedhoff, Michal (Markey)
Cc: Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,
Revised TA on section 19 with house changes annotated.

Section 19 – Sec. 19.XML comments
Page 1 – remove all brackets DONE

Page 1 line 6 to 19 -- consolidate this material in paragraph (a)(1), perhaps as a new (a)(1)(C). Per EPA TA to ensure that low priority decisions are covered by the judicial review provisions of subsection (c). DONE

Page 2 line 9 – remove brackets from "Except as otherwise provided by this title" DONE

Page 2 line 13 – remove brackets from " 6(i)(1)" DONE

Page 2 lines 18 to 25 – remove all brackets DONE

Page 3 line 6 – remove brackets from "6(i)(1)" DONE

Page 4, line 2– strike lines 2 through 21, and insert:
"by amending subsection (c)(1)(B)(i) to read: "(i) in the case of review of a rule under section 4(a), 5(b)(4), 6(a) (including review of the associated determination under section 6(b)(4)(A)) or 6(e), or an order under 6(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule or order if the court finds that the rule or order is not supported by substantial evidence in the record including any matter in the record taken as a whole;" DONE EXCEPT SUBSTANTIAL EVIDENCE DIRECTION FOR RULES AND ORDERS IS DIVIDED INTO SEPARATE SUBCLAUSES AND REVIEW OF TEST ORDERS UNDER SECTION 4 IS ADDED TO SUBSTANTIAL EVIDENCE REVIEW.

Page 5 line 7-8 – Strike the brackets before (iii) DONE

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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On Apr 23, 2016, at 4:30 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just verifying before proceeding that you checked conforming edits at the end of the bill?

Michal Ilana Freedhoff, Ph.D.
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Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 4:29 PM
To: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,
While we continue to work on the TA requests on 14 and other sections, we wanted to pass along TA on house section 19 (4-23).

The House discussion draft leaves section 19 from current TSCA un-amended, except for the addition of judicial review of low-priority determinations. Thus, in contrast to the Senate bill and offer, it does not:

-- provide for judicial review of test orders under section 19

-- provide for judicial review of rules other than the rules currently enumerated in section 19

-- provide for judicial review of determinations that a chemical substance does not present unreasonable risk under section 19 (including the substantial evidence review the senate bill and offer would afford).

Note that this does not mean that these EPA actions will not be judicially reviewable. Rather, they would be reviewable in federal district court, rather than the court of appeals, and would be subject to the general federal 6-year review period, rather than the 60 days provided for in section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 3:25:19 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on house Section 4

Michal- we're not sure that house 4 is so bad. The adds at the end might save it. Can you call again Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy

On Apr 5, 2016, at 10:29 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thank you. ai am re-drafting yet another section 4, pls stand by for that in the next hour or so I hope.

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Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 05, 2016 10:26 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on Section 5 - early morning

Michal – TA responding to your comments on section 5 attached. EPA comments in blue. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 05, 2016 6:00 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Section 5

Sven - comments in yellow are for you, changes marked with blank comment boxes and a couple in green for Dimitri. Pls take one more FAST look, need to get this to the House asap.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 6:59:26 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,
This TA responds to the request on chem ID.

Here are the regulations governing CBI claims for the identity of chemical substances contained in health and safety studies where those substances are the subject of Premanufacture Notices under Section 5. Those regulations, at 40 CFR 720.90, contain an exception from disclosure where the specific chemical identity is not necessary to interpret a health and safety study. See 720.90(c):

(c) *Denial of confidentiality claim.* EPA will deny a claim of confidentiality for chemical identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the information would disclose the portion of the mixture comprised by any of the substances in the mixture.

(3) The specific chemical identity is not necessary to interpret a health and safety study.

For your reference, EPA's general TSCA confidentiality regulations at 40 CFR 2.306 do not include this exception from disclosure of information from health and safety studies, and EPA's regulations regarding health and safety studies submitted under TSCA section (8)(d) at 40 CFR part 716 state that chemical identity is part of, or underlying data to, a health and safety study. 40 CFR 716.3.

Also, per request, here is a proposed revision of the most recent language you provided regarding health and safety studies in section 14(b)(1). This would provide protection for confidential chemical identities contained in health and safety studies of uncommenced PMNs substances, but eliminate such special protection once manufacture or processing has commenced such that the chem IDs would be releasable at that point unless they meet one of the two statutory bases for withholding (process information and proportions-of-mixtures information).

(b) Information Not Protected From Disclosure.—

"(1) DATA FROM HEALTH AND SAFETY STUDIES.—Subsection (a) does not prohibit the disclosure of—

(A) any health and safety study which is submitted under this chapter with respect to—

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or

(ii) any chemical substance or mixture for which testing is required under section 2603 of this title or for which notification is required under section 2604 of this title, and

(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture ~~or~~, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture, or the specific identity of a chemical substance or mixture for which notification is required under section 2604 of this title and which has not been offered for commercial distribution.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 13, 2016 11:14 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: ChemID question

Can you send me the regulations for how epa decides when to protect chemID in a health and safety study when it does NOT fall into the process/concentrations categories that allow protection? I'm trying to understand how epa decides these cases that are not automatically protected in HS studies - is it case by case? On what basis?
Thanks

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/2/2016 2:09:35 AM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]
Subject: HEC TSCA TA on House 6(c)(1)(B)

Dave,
This TA responds to the request on 6(c)(1)(B). Please let me know if any questions. Thanks,
Sven

TA Request: Impact of draft 6(c)(1)(B) including adding "reasonably"

House bill "(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are reasonably necessary to protect against the identified risk."

Response: We believe the addition of "reasonably" probably marginally reduces the burden on EPA to demonstrate that non-cost-effective requirements are necessary.

That said, this addition does not address the other points EPA has made in technical assistance on this provision. Specifically:

1. The provision states that EPA's determination of cost-effectiveness must be "consistent with the information published under subparagraph (A)". We do not believe that clearly circumscribes the extent of the information EPA must assess in judging cost-effectiveness. If the intention is to provide that the information EPA is required to assess in assessing cost-effectiveness is limited to the information published under subparagraph (A), it would be clearer if the provision stated that the determination must be "*based on* the information published under subparagraph (A)."

2. On a related issue, the scope of the analysis EPA would be required to undertake is unclear. Since EPA can impose non-cost-effective requirements only where such requirements are necessary (or reasonably necessary), it could be argued that EPA could not make such a showing without first identifying and rejecting all possible cost-effective requirements.

3. The protectiveness standard in the provision – "[reasonably] necessary to protect against the identified risk" – is different from the protectiveness standard in section 6(a) of the House bill. Thus, it could be argued that the standard when EPA imposes non-cost-effective requirements is in some way different from the general section 6(a) rulemaking standard.

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 8:00:05 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Section 19
Attachments: Markey.TSCA TA.section 19.4.8.16.doc

Michal,
This TA responds to the request on section 19. We don't see any inconsistency between TA we sent to you and TA we sent to Dmitri. In any event, attached is our TA on the revised section you sent.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 7, 2016 at 8:43:34 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Cc: "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>, "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Subject: Section 19

Sven

I'm having trouble reconciling the TA you sent Dimitri (pasted below) with the TA you sent me when I asked for the rest of the Senate-offer conforming changes to 19 (attached). You sent me some changes to cross-refs in the same section of text that you helped Dimitri with, and the cross-references don't seem to match up or maybe I am misunderstanding. Could you take a look at this whole section, with particular attention paid to the yellow highlighted text?

Thanks
Michal

The TA you sent Dimitri:
That said, option 1 is largely harmless if properly edited. To be consistent with the overall structure of the Senate bill, it should read: "section 4(a), 6(d) (including review of **the** associated determination under section 6(c)(1)(B)), or 6(**h**), or an order under section 6(c)(1)(A)." The definite article is to maintain consistency with 6(f)(2), which refers to "the associated safety assessment and safety determination." Referring to "an associated determination" could

give rise to arguments that other safety determinations (i.e., other than the one that gave rise to the risk management rule) are sufficiently associated with the rule that they should be reviewed as part of the risk management rule.

This language is provided EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. 19. JUDICIAL REVIEW.

(a) IN GENERAL.—(1)(A) Except as otherwise provided in this title, ~~N~~not later than 60 days after the date of the promulgation of a rule under this title ~~section 4(a), 5(a)(2), 5(b)(4), 6(a), 4(a), 5(d), 6(c), 6(d), 6(ge), or 8,~~ or ~~under~~ title II or IV, or an order under section 4 or 6(i)(1), any person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule or order if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Except as otherwise provided in this title, ~~C~~courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under this title other than an order under section 4 or 6(i)(1) ~~subparagraph (A) or (B) of section 6(b)(1)~~ if any district court of the United States would have had jurisdiction of such action but for this ~~sub~~paragraph.

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28, United States Code, shall apply to the filing of the ~~rulemaking~~ record of proceedings on which the Administrator based the rule or order being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(3) JUDICIAL REVIEW OF LOW-PRIORITY DESIGNATIONS.—

(A) IN GENERAL.—Not later than 60 days after the publication of a designation under section 6(b)(1)(B)(ii), any person may commence a civil action to challenge the designation.

(B) JURISDICTION.—The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this paragraph.

~~(3) For purposes of this section, the term ''rulemaking record'' means—~~

~~(A) the rule being reviewed under this section;~~

~~(B) in the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such~~

Commented [A1]: "or for" is missing after "Circuit". Why is the base text not just copied from TSCA? We have not carefully reviewed base text.

Commented [A2]: It would be better to consolidate this into (a)(1). Aside from the unnecessary extra paragraph, the placement of this in a separate paragraph means review of low priority decisions is not covered by the judicial review provisions of (c). That's probably ok, but is there any reason for that?

This language is provided EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

~~section, as the case may be[1] and in the case of a rule under title IV, the finding required for the issuance of such a rule;~~

~~(C) any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;~~

~~(D) any written submission of interested parties respecting the promulgation of such rule; and~~

~~(E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the Federal Register.~~

(b) ADDITIONAL SUBMISSIONS AND PRESENTATIONS; MODIFICATIONS.— If in an action under this section to review a rule, or an order under section 4 or 6(i)(1), the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule or order and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule or order being reviewed or make a new rule or order by reason of the additional submissions and presentations and shall file such modified or new rule or order with the return of such submissions and presentations. The court shall thereafter review such new or modified rule or order.

(c) STANDARD OF REVIEW.—(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and (ii) except as otherwise provided in subparagraph (B), to review such rule in accordance with chapter 7 of title 5, United States Code.

(B) Section 706 of title 5, United States Code, shall apply to review of a rule under this section, except that—

(i) in the case of review of a rule under section 4(a), 6(a) (including review of the associated determination under section 6(c)(1)(B)), or 6(e), or an order under section 6(i)(1), ~~4(a), 5(b)(4), 6(a), or 6(e),~~ the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule or order if the court finds that the rule or order is not supported by substantial evidence (including any matter) in the ~~rulemaking~~ record, ~~(as defined in subsection (a)(3))~~ taken as a whole; and

(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be

Commented [A3]: The citations in this document seem to be to the senate offer, except for this one, which seems to be to the senate bill. If you are working off the senate offer, this citation should presumably be to 6(b)(4)(A).

~~[1] So in law. Probably should be followed by a comma.~~

This language is provided EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

~~incorporated in the rule or order, except as part of the rulemaking record, taken as a whole.~~

~~(ii) in the case of review of a rule under section 6(a), the court shall hold unlawful and set aside such rule if it finds that—~~

~~(I) a determination by the Administrator under section 6(c)(3) that the petitioner seeking review of such rule is not entitled to conduct (or have conducted) cross-examination or to present rebuttal submissions, or~~

~~(II) a rule of, or ruling by, the Administrator under section 6(c)(3) limiting such petitioner's cross-examination or oral presentations,~~

~~has precluded disclosure of disputed material facts which was necessary to a fair determination by the Administrator of the rulemaking proceeding taken as a whole, and section 706(2)(D) shall not apply with respect to a determination, rule, or ruling referred to in subclause (I) or (II); and~~

~~(iii) the court may not review the contents and adequacy of—~~

~~(I) any statement required to be made pursuant to section 6(c)(1), or~~

~~(II) any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule~~

~~except as part of a review of the rulemaking record taken as a whole.~~

~~The term ''evidence'' as used in clause (i) means any matter in the rulemaking record.~~

~~(C) A determination, rule, order, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph.~~

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) FEES AND COSTS.—The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) OTHER REMEDIES.—The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.
[15 U.S.C. 2618]

Commented [A4]: It is probably harmless to retain this, but it is superfluous and could be confusing. This is adapted from current TSCA, which applies to both the 553(c) statement and the statement require by current TSCA 6(c). The latter provision has been deleted from the bill and hence deleted from this clause. This clause is presented as an exception to the APA, but it's now not an exception: the statement of basis and purpose required by the APA is only reviewable as part of the record as a whole even without this provision. If this is to be retained, it would be better as a free-standing (superfluous) provision, rather than being presented as an exception to the APA.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/28/2016 10:36:29 AM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on costs analysis
Attachments: Markey.TSCA TA.Costs Analysis.Senate Offer 4 24 RLSO of HLC 4 22.docx; Markey.TSCA TA.Costs Analysis.Senate Offer 4.24 - Section 5.docx

Michal,
Resend with both documents attached. Please let me know if any questions. Thank,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Wednesday, April 27, 2016 9:04 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request on costs analysis

Michal,
This TA responds to the request on cost considerations.

In particular, there are three comments to point out. The most important is the comment on p. 49 [44] of the second document (RLSO of HLC 4 22), which addresses the cost analysis issue for alternatives we have discussed.

The other two are on p. 137 [124] of that document (addressing discrepancies in the drafting of section 21) and p. 8 of the first document (suggesting text to align the sec 5 review period with the obligation to respond to information submitted).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

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Washington, DC 20460

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[DISCUSSION DRAFT]

114TH CONGRESS
2D SESSION

H. R. ||

To ø modernize the Toxic Substances Control Act, and for other purposes ¿.

IN THE HOUSE OF REPRESENTATIVES

Mr. ||||||| introduced the following bill; which was referred to the Committee on
|||||||||||||

A BILL

To ø modernize the Toxic Substances Control Act, and for other purposes ¿.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended by striking "proposes to take" and inserting "proposes as provided".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4) through (14) as paragraphs (5), (6), (8), (9), (10), (11), (13), (14), (15), (16), and (17), respectively;

(2) by inserting after paragraph (3) the following:

"(4) The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reason-

ably foreseen to be manufactured, processed, distributed in commerce, used, ~~and~~ or disposed of.";

(3) by inserting after paragraph (6), as so redesignated, the following:

"(7) The term 'guidance' means any significant written guidance of general applicability prepared by the Administrator."; and

(4) by inserting after paragraph (11), as so redesignated, the following:

"(12) The term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.".

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking "standards" each place it appears and inserting "protocols and methodologies";

(2) in subsection (a)—

(A) by striking "If the Administrator finds" and inserting "(1) If the Administrator finds";

(B) in paragraph (1), as so designated—

(i) by striking "(1)(A)(i)" and inserting "(A)(i)(I)";

(ii) by striking "(ii)" each place it appears and inserting "(II)";

(iii) by striking "are insufficient data" and inserting "is insufficient information" each place it appears;

(iv) by striking "(iii)" each place it appears and inserting "(III)";

(v) by striking "such data" and inserting "such information" each place it appears;

(vi) by striking "(B)(i)" and inserting "(ii)(I)";

(vii) by striking "(I)" and inserting "(aa)";

(viii) by striking "(II)" and inserting "(bb)";

(ix) by striking "(2)" and inserting "(B)"; and

(x) in the matter following subparagraph (B), as so redesignated—

(I) by inserting ", or, in the case of a chemical substance described in subparagraph (A)(i), by rule or order," after "rule"; and

(II) by striking "data" each place it appears and inserting "information"; and

(C) by adding at the end the following:

"(2) ADDITIONAL TESTING AUTHORITY.—In addition to the authority provided under paragraph (1), the Administrator may, by rule, order, or consent agreement—

"(A) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary—

"(i) to review a notice under section 5~~(d)~~ or to perform a risk evaluation under section 6(b);

"(ii) to implement a requirement imposed in a rule, order, or consent agreement under subsection (e) or (f) of section

5 or under a rule promulgated under section 6(a); or

"(iii) at the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure; and

(iv) 12(a)(2) testing authority

Commented [A1]: Wording needs fixing.

"(B) require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that such information is necessary to establish the priority of the substance, subject to the limitations that—

"(i) not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or consent agreement under this subparagraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance; and

"(ii) information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum infor-

mation requirement of broader applicability.

"(3) STATEMENT OF NEED.—When requiring the development of new information relating to a chemical substance or mixture under paragraph (2), the Administrator shall identify the reasonable basis for concern about the chemical substance or mixture and the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

"(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall ~~consider~~ employ~~ing~~ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first ~~considering~~ conducting~~;~~ screening-level testing.";

(3) in subsection (b)—

Insert (A) in the header to subsection (b), insert ",order or consent agreement" and renumber (A) and subsequent paragraphs accordingly

Commented [A2]: Can't follow heading designations but substance seems fine

(A) in paragraph (1)—

(i) in subparagraph (B), by striking "test data" and inserting "information";

(ii) in subparagraph (C), by striking "data" and inserting "information"; and

(iii) in the matter following subparagraph (C), by striking "data" and inserting "information";

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information";

(II) by inserting "Protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential to humans or the environment." after the first sentence; and

(III) by striking "hierarchical tests" and inserting "tiered testing"; and

(ii) in subparagraph (B), by striking

"data" and inserting "information";

(C) in paragraph (3)—

(i) by striking "data" each place it appears and inserting "information"; ~~and~~

(ii) by striking "(a)(1)(A)(ii) or (a)(1)(B)(ii)" each place it appears and inserting "(a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II)"; and

(iii) in subparagraph (3)(A), insert "or order" after "rule";
(iv) following "subparagraph (B)" insert "or (C), as applicable,"
(v) at the end of subparagraph (3)(B), in the matter before (3)(B)(i), strike "subsection (a)" and insert "subsection (a)(1)"; and
(vi) at the end of subparagraph (3)(B), insert "(C) a rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order."

"(C) A rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would require several minor conforming changes to (b)(3).

Commented [A3]: This looks like the EPA TA, and repeats (C). Presumably this would not be codified.

(D) in paragraph (4)—

(i) by striking "of data" each place it appears and inserting "of information"; and

(ii) by striking "test data" each place it appears and inserting "information"; and

(E) by striking paragraph (5);

(4) in subsection (c)—

(A) in paragraph (1), by striking "data" and inserting "information";

(B) in paragraph (2), by striking "data"

each place it appears and inserting "information";

(C) in paragraph (3)—

(i) by striking "test data" each place it appears and inserting "information"; and

(ii) by striking "such data" each place it appears and inserting "such information"; and

(D) in paragraph (4) by striking "test data" each place it appears and inserting "information";

(5) in subsection (d)—

(A) by striking "test data" each place it appears and inserting "information";

(B) by striking "such data" each place it appears and inserting "such information"; and

(C) by striking "for which data have" and inserting "for which information has";

(6) in subsection (e)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "promulgation of a rule" and inserting "development of information"; and

(II) by striking "data" each place it appears and inserting "information"; and

(ii) in subparagraph (B), by striking "either initiate a rulemaking proceeding under subsection (a) or if such a pro-

ceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding" and insert "issue an order, enter into a consent agreement, or initiate a rulemaking proceeding under subsection (a), or, if such an order or consent agreement is not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order, entering into such a consent agreement, or initiating such a proceeding"; and

(B) in paragraph (2)(A)—

(i) by striking "eight members" and inserting "ten members"; and

(ii) by adding at the end the following:

"(ix) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

"(x) One member appointed by the Commissioner of Food and Drugs from employees of the Food and Drug Administration.";

(7) in subsection (f)—

(A) in paragraph (1), by striking "test data" and inserting "information"; and

(B) in the matter following paragraph (2)—

(i) by striking "from cancer, gene mutations, or birth defects";

(ii) by striking "data or";

(iii) by striking "appropriate" and inserting "applicable"; and

(iv) by inserting ", made without consideration of costs or other nonrisk factors," after "publish in the Federal Register a finding";

(8) in subsection (g)—

"(g) Renamed 'Petition for protocols and methodologies for the development of information'"

(A) by striking "test data" each place it appears and inserting "information"; and

(B) by striking "submit data" and inserting "submit information"; and

(9) by adding at the end the following:

"(h) REDUCTION OF TESTING ON VERTEBRATES.

[Senate: Animal testing still needs to be resolved]

"(1) IN GENERAL.—The Administrator shall reduce, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical

substances or mixtures under this title by—

"(A) when making a request or adopting a requirement for testing using vertebrate animals, and in accordance with subsection (a)(3), taking into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics; and

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(B) encouraging and facilitating—

"(i) the use of scientifically valid test methods and strategies that reduce the use of vertebrate animals while providing information of equivalent or better scientific quality and relevance that will support regulatory decisions under this title;

"(ii) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on

other chemical substances in the category; and

"(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests, provided that such consortia make data from such testing available to the Administrator.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new scientifically valid test methods and strategies that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures through, for example—

"(i) computational toxicology and bioinformatics;

"(ii) high-throughput screening methods;

"(iii) testing of categories of chemical substances;

"(iv) tiered testing methods;

"(v) in vitro studies;

"(vi) systems biology;

"(vii) new or revised methods identified by validation bodies such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Co-operation and Development; or

"(viii) industry consortia that develop information submitted under this title;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) include in the strategic plan developed under subparagraph (A) a list, which the Administrator shall update on a regular basis, of particular alternative test methods or strategies the Administrator has identified that do not require new vertebrate animal testing and

are scientifically reliable, relevant, and capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing for specific health and environmental endpoints;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific relevance and value for risk assessment purposes of the test methods and strategies that may be identified pursuant to subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing the plan developed under subparagraph (A) and goals for future alternative test methods and strategies implementation; and

"(F) prioritize and, to the extent consistent with available resources and the Administrator's other responsibilities under this title,

carry out performance assessment, validation, and translational studies to accelerate the development of scientifically valid test methods and strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this title.".

[Section 5 replaced with HLC 4.18 and line edits – in separate document]

~~SEC. 5. MANUFACTURING AND PROCESSING NOTICES.~~

~~Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—~~

~~(1) in subsection (a)—~~

~~(A) in paragraph (1)—~~

~~(i) by striking "Except as provided in" and inserting "(A) Except as provided in subparagraph (B) of this paragraph and";~~

~~(ii) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;~~

~~(iii) by striking all that follows "significant new use" and inserting a period; and~~

~~(iv) by adding at the end the following:~~

~~"(B) A person may take the actions described in subparagraph (A) if—~~

~~"(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement imposed under subsection (b), (c), or (f); and~~

~~"(ii) the Administrator—~~

~~"(I) conducts a review of the notice; and~~

~~"(II) makes a determination under subparagraph (A), (B), (C), (D), or (E) of paragraph (3) and takes the actions required in association with that determination under such subparagraph."; and~~

~~(B) by adding at the end the following new paragraphs:~~

~~"(3) REVIEW AND DETERMINATION.—Not later than 90 days after receipt of a notice under paragraph (1), subject to section 18, the Administrator shall review such notice and determine—~~

~~"(A) that the relevant chemical substance or significant new use presents or will present an unreasonable risk of injury to health or the~~

~~environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take applicable action under subsection (f);~~

~~"(B) that the relevant chemical substance or significant new use is likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall—~~

~~"(i) by consent agreement or order, prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, such that the Administrator determines that compliance with such prohibition or restrictions is sufficient to ensure that the chemical~~

~~substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment; and~~

~~"(ii) take applicable action under paragraphs (4) through (8) of subsection (f);~~

~~"(C) that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs, or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take applicable action under subsection (e);~~

~~"(D) that the relevant chemical substance or significant new use is likely not to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall publish such~~

~~determination and the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use; or~~

~~"(E) that the relevant chemical substance is a low-hazard substance, in which case the Administrator shall publish such determination and the submitter of the notice may commence manufacture or processing of the chemical substance.~~

~~"(4) FAILURE TO RENDER DETERMINATION.—~~

~~"(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Administrator shall not be relieved of any requirement to make such determination.~~

~~"(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the~~

~~submitter has not provided information required under subsection (b) or (c) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review.~~

~~"(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.~~

~~"(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.~~

~~"(5) ARTICLE CONSIDERATION.—In promulgating a rule under paragraph (2), the Administrator shall consider whether there is a likely potential for exposure to a chemical substance through an article or category of articles, and if the Administrator finds such a likely potential, the Administrator shall require notification under this section for the import or processing of a chemical substance as part of the article or category of articles.";~~

~~(2) in subsection (b)—~~

~~(A) in the subsection heading, by striking "TEST DATA" and inserting "INFORMATION";~~

~~(B) in paragraph (1)—~~

~~(i) in subparagraph (A)—~~

~~(I) by striking "test data" and inserting "information"; and~~

~~(II) by striking "such data" and inserting "such information"; and~~

~~(ii) in subparagraph (B)—~~

~~(I) by striking "test data" and inserting "information";~~

~~(II) by striking "subsection (a)(1)(A)" and inserting "subsection (a)(1)(A)(i)"; and~~

~~(III) by striking "subsection (a)(1)(B)" and inserting "subsection (a)(1)(A)(ii)";~~

~~(C) in paragraph (2)—~~

~~(i) in subparagraph (A)—~~

~~(I) by striking "test data" in clause (ii) and inserting "information";~~

~~(II) by striking "shall" and inserting "may"; and~~

~~(III) by striking "data prescribed" and inserting "information prescribed"; and~~

~~(ii) in subparagraph (B)—~~

~~(I) by striking "Data" and inserting "Information";~~

~~(II) by striking "data" both places it appears and inserting "information";~~

~~(III) by striking "show" and inserting "shows";~~

~~(IV) by striking "subsection (a)(1)(A)" in clause (i) and inserting "subsection (a)(1)(A)(i)"; and~~

~~(V) by striking "subsection (a)(1)(B)" in clause (ii) and inserting "subsection (a)(1)(A)(ii)";~~

~~(D) in paragraph (3)—~~

~~(i) by striking "Data" and inserting "Information"; and~~

~~(ii) by striking "paragraph (1) or (2)" and inserting "paragraph (1) or (2) of this subsection or under subsection (e)"; and~~

~~(E) in paragraph (4)—~~

~~(i) in subparagraph (A)(i), by inserting ", without consideration of costs or other nonrisk factors" after "health or the environment"; and~~

~~(ii) in subparagraph (C), by striking ", except that" and all that follows through "subparagraph (A)";~~

~~(3) in subsection (c)—~~

~~(A) in the subsection heading, by inserting "AND REVIEW" after "NOTICE"; and~~

~~(B) by striking "before which" and all that follows through "subsection may begin";~~

~~(4) in subsection (d)—~~

~~(A) by striking "test data" in paragraph (1)(B) and inserting "information";~~

~~(B) by striking "data" each place it appears in paragraph (1)(C) and paragraph (2) and inserting "information";~~

~~(C) in paragraph (2)(B), by striking "uses or intended uses of such substance" and inserting "uses of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator"; and~~

~~(D) in paragraph (3)—~~

~~(i) by striking "for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "for which the applicable review period"; and~~

~~(ii) by striking "such notification period" and inserting "such period";~~

~~(5) in subsection (e)(1)(A), by inserting "under subsection (a)(3)(C)" after "If the Administrator determines";~~

~~(6) in subsection (f)—~~

~~(A) in paragraph (2), by striking "section 6(d)(2)(B)" and inserting "section 6(c)(3)"; and~~

~~(B) by adding at the end the following:~~

~~"(4) PROHIBITION.—If the Administrator makes a determination under subsection (a)(3)(A) or (B) with respect to a chemical substance or a significant new use, no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection except in compliance with the restrictions specified in a rule promulgated under paragraph (2).~~

~~"(5) TREATMENT OF NONCONFORMING USES.—Not later than 90 days after taking an action under paragraph (2) or (3) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to~~

promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(6) SELECTING PROHIBITIONS AND RESTRICTIONS.—In selecting among prohibitions and other restrictions, relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other nonrisk factors, and such an order shall include a requirement described in section 6(a).

"(7) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) that the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or

~~moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance to the extent practicable.~~

~~"(8) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.";~~

~~(7) by amending subsection (g) to read as follows:~~

~~"(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds, in accordance with subsection (a)(3)(D), that a chemical substance or significant new use is likely not to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the sub-~~

~~mitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.";~~

~~(8) in subsection (h)—~~

~~(A) in paragraph (1)(A), by inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific uses identified in the application" after "health or the environment";~~

~~(B) in paragraph (2), by striking "data" each place it appears and inserting "information"; and~~

~~(C) in paragraph (4), by striking ". A rule promulgated" and all that follows through "section 6(c)" and inserting ", including an unreasonable risk to a potentially exposed or suscep-~~

~~tible subpopulation identified by the Administrator under the conditions of use"; and~~

~~(9) by amending subsection (i) to read as follows:~~

~~"(i) DEFINITIONS.—(1) For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.~~

~~"(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.~~

~~"(3) For purposes of this section, the term 'applicable review period' means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending on the date the Administrator makes a determination under subsection (a)(3), as extended pursuant to subsection (c) or (e)(1)(A).".~~

SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section heading and inserting "**PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES**";

(2) in subsection (a)—

(A) by striking "finds that there is a reasonable basis to conclude that" and inserting "determines in accordance with subsection (b)(4)(A)";

(B) by inserting "and subject to section 18, and in accordance with subsection (c)(2)," after "shall by rule";

(C) by striking "to protect adequately against such risk using the least burdensome requirements" and inserting "so that the chemical substance no longer presents such risk";

(D) by inserting "or otherwise restricting" after "prohibiting" in paragraph (2)(A);

(E) by inserting "minimum" before "warnings" both places it appears in paragraph (3);

~~(F) by striking "and monitor or conduct tests" and inserting "or monitor or conduct tests pursuant to section 4" in paragraph (4); and~~

(G) in paragraph (7)—

(i) by striking "such unreasonable risk of injury" and inserting "such determination"; and

(ii) by striking "such risk of injury" and inserting "such determination";

(3) by amending subsection (b) to read as follows:

"(b) RISK EVALUATIONS.—

"(1) PRIORITIZATION FOR RISK EVALUATIONS.—

"(A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use

of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

"(B) IDENTIFICATION OF PRIORITIES FOR RISK EVALUATION.—

"(i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

"(ii) LOW-PRIORITY SUBSTANCES.—The Administrator shall designate as a low-priority substance a chemical substance with respect to which the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that the

chemical substance is likely not to present an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

"(C) The Administrator shall, in the rulemaking required under paragraph (1)(A) notify the public of when the prioritization begins, and provide an opportunity for comment, for each chemical substance and ensure that the time required to make a priority designation of a chemical substance be no longer than 1 year"

"(D) "The Administrator shall, in the rulemaking required under paragraph (1)(A), provide for a process to extend the deadline under subparagraph C for up to six months in order to receive or evaluate information required to be submitted in accordance with section 4(a)(2)(B), subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the substance as high-priority substance"

"(E) The Administrator shall publish each designation of a chemical substance as a high or low priority substance along with an identification of the information, analysis, and basis used to make the designations"

Commented [A4]: This doesn't make sense. The rulemaking under (1)(A) is to establish the general prioritization procedures. That one rulemaking cannot notify the public of every future date on which every chemical substance will ever be prioritized under TSCA. The prioritization of a particular chemical substance is a subsequent event, and it is not a rulemaking event.

What is meant here is that EPA should, in the (1)(A) rule, impose on itself an obligation to later provide the notice and comment, according to the specified parameters.

Solution:

"under paragraph (1)(A) provide for a process whereby it must notify . . ."

"(2) INITIAL RISK EVALUATIONS AND SUBSEQUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) INITIAL RISK EVALUATIONS.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 10 chemical substances

drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

"(B) ADDITIONAL RISK EVALUATIONS.—Not later than three and one half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chem-

ical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

"(C) CONTINUING DESIGNATIONS AND RISK EVALUATIONS.—The Administrator shall continue to designate priority substances ~~and conduct risk evaluations in accordance with this subsection~~, subject to the limitation described in subparagraph (B)~~.~~ until all substances drawn from the 2014 update of the TSCA Work plan for Chemical Assessments have undergone risk evaluations, and until the priority of all chemical substances have been designated, at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

"(D) PREFERENCE.—In designating high-priority substances, the Administrator shall give preference to—

"(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and

"(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are

Commented [A5]: C now addresses only prioritization, so title is overbroad

Commented [A6]: The limitation described in B relates to risk evaluations, not prioritization, so this makes less sense now that the text in lines 11-13 has been stricken and this provision addresses only prioritization.

Commented [A7]: This adds back in the awkwardness of prioritizing WP chems with a pre-determined outcome, and the impossibility of complying with the (B) limitation re proportion of PBTs once the PBTs are done.

Commented [A8]: The "and" should be dropped. As we understand this, the preceding clause ("until all substances. . . .") delimits just the period under which the B limitation is applicable, and the following clause ("until the priority. . . .") delimits the period during which prioritization must continue. They address different question. As written, we read this to say "The Administrator shall continue to designate high priority substances. . . and until the priority of all chemical substances has been designated . . ."

Commented [A9]: Should be "has"

Commented [A10]: This seems like unnecessary direction. The bill already requires the high priority list to be refreshed on a 1-for-1 basis as risk evaluations are completed. This seems like additional but softer direction. That observation applies to (C) generally – it is not necessary to ensure continued prioritization and creates the issues identified above.

known human carcinogens and have high acute and chronic toxicity.

"(E) METALS AND METAL COMPOUNDS.—In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

"(3) INITIATION OF RISK EVALUATIONS; DESIGNATIONS.—

"(A) RISK EVALUATION INITIATION.—Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

"(B) REVISION.—The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

"(C) ONGOING DESIGNATIONS.—The Administrator shall designate at least one high-priority substance upon the completion of each

risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

"(4) RISK EVALUATION PROCESS AND DEADLINES.—

"(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

"(B) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

"(C) REQUIREMENT.—The Administrator shall conduct and publish risk evaluations, in

accordance with the rule promulgated under subparagraph (B), for a chemical substance—

"(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

"(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

"(D) SCOPE.—The Administrator shall, as soon as practicable and not later than 6 months after each designation of a high-priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider.

"(E) LIMITATION AND CRITERIA.—

"(i) PERCENTAGE REQUIREMENTS.—

The Administrator shall ensure that, of the number of [note: substantive edit to make RE %age work]

chemical substances that undergo a risk evaluation under clause (i) of subpara-

graph (C), the percentage of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is—

"(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

"(II) not more than 50 percent.

"(ii) REQUESTED RISK EVALUATIONS.—Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 26(b)(3)(D), and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

"(iii) PREFERENCE.—In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

Commented [A11]: Edit above is helpful, but "percentage" here should also be changed to "number". Otherwise EPA is being told to calculate a percentage by taking some other percentage and dividing it by the number of EPA priority chems under way, and there is no direction about how to calculate that other percentage.

"(iv) EXCEPTIONS.—(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) and that are not drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall not be subject to section 18(b).

"(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

"(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

"(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

"(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

"(iii) not consider costs or other nonrisk factors;

"(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

"(v) describe the weight of the scientific evidence for the identified hazard and exposure.

"(G) DEADLINES.—The Administrator—

"(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates ~~a~~ the risk evaluation under subparagraph (C); and

"(ii) may extend the deadline for a risk evaluation for not more than 1 year, if information relating to the chemical substance is required to be developed in a rule,

order, or consent agreement under section 4 and has not yet been submitted to the Administrator, or if such information has been submitted to the Administrator within the time specified in the rule, order, or consent agreement and on or after the date that is 120 days before the expiration of the deadline described in clause (i).

"(H) NOTICE AND COMMENT.—The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.";

(4) by amending subsection (c) to read as follows:

"(c) PROMULGATION OF SUBSECTION (a) RULES.—

"(1) DEADLINES.—If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator—

"(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date

on which the final risk evaluation regarding the chemical substance is published;

"(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

"(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the

Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

"(2) REQUIREMENTS FOR RULE.—

"(A) STATEMENT OF EFFECTS.—In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

"(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture as identified by the Administrator in the risk evaluation;

"(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture as identified by the Administrator in the risk evaluation;

"(iii) the benefits of the chemical substance or mixture for various uses; and

"(iv) the reasonably ascertainable economic consequences of the ~~rule~~ proposed and final regulatory action and the considered alternatives, including

Commented [A12]: Our understanding is that this language was modified in response to an EPA suggestion that the text of (iv) could be better aligned with the text of II and III. However, the new text creates additional alignment issues, by using different words in (iv) than in (II) and (III) to describe the alternatives EPA must consider; and it could be read to expand the required analysis for alternatives. We understand that was not the intent. Two suggestions for addressing this:

1.Retain "proposed and final regulatory action" but drop "and the considered alternatives". This approach would best ensure against unintended expansion of alternatives analysis.

2.Retain "proposed and final regulatory action" but replace "and the considered alternatives" with ", and of the one more primary alternative regulatory actions considered by the Administrator as provided in subclauses (II) and (III),"

consideration of—

"(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

"(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

"(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) SELECTING REQUIREMENTS.—In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A).

"(C) CONSIDERATION OF ALTERNATIVES.—Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture, and in setting an appropriate

transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

"(D) REPLACEMENT PARTS.—

"(i) IN GENERAL.—For complex durable goods and complex consumer goods, the Administrator shall exempt replacement parts that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A)? for the chemical substance or for a chemical substance contained in a mixture, to the general population or to an identified potentially exposed or susceptible subpopulation.

Commented [A13]: (b)(4)(A) is the right citation; but there is an inconsistency in the bill about whether the formulation is "under subsection (b)(4)(A)" or "in accordance with (b)(4)(A)" or "pursuant to subsection (b)(4)(A)"

"(ii) DEFINITIONS.—In this subparagraph—

"(I) the term 'complex consumer goods' means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

"(II) the term 'complex durable goods' means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

"(E) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical

substance or mixture from the article or category of articles, so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

?? Page 47 line 19 – proposal to delete second instance of "category of articles" as described as redundant – per EPA TA this is not redundant and deleting this would significantly increase the burden on the Agency.

Commented [A14]: There may be some confusion about this. We were asked by Senate staff whether there was a problem with deleting the second "or category of articles" and said (correctly) there was. HLC though deleted the entire phrase "from the article or category of articles", which we would have no concern about. Not sure if Senate staff added back in that entire phrase because they thought EPA saw it as important.

"(3) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also—

"(A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule;

"(B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

"(C) promulgate a final rule based on the matter in the rulemaking record; and

"(D) make and publish with the rule the determination described in subsection (a).";

~~(5) by amending subsection (d) to read as follows:~~

Commented [A15]: Will need to add back in some statement that subsection d is being amended.

"(d) EFFECTIVE DATE.—

(A) amend paragraph (1) to read as follows:

"(1) IN GENERAL.—In any rule under subsection (a), the Administrator shall—

"(A) specify the date on which it shall take effect, which date shall be as soon as practicable;

"(B) except as provided in subparagraph (C), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);

"(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

"(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

"(E) provide for a reasonable transition period.

(B) Insert a new paragraph (2) to read as follows:

"(2) VARIABILITY.—As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.";

(C) redesignate paragraph (2) as paragraph (3) and make the following changes:

"(i) in subparagraph (A)(i)(II), as so redesignated— insert "without consideration of costs or other nonrisk factors" after "such effective date"; and
(ii) in subparagraph (B)—
(I) by striking "provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule," and inserting "in accordance with paragraph (3) of subsection (c),"; and
(II) by striking "; and if such a hearing" and all that follows through" or revoke it";

Commented [A16]: Should be (A)(i)(I)

(6) in subsection (e)(4), by striking "paragraphs (2), (3), and (4)" and inserting "paragraph (3)"; and

(7) by adding at the end the following new subsections:

"(g) EXEMPTIONS.—

"(1) CRITERIA FOR EXEMPTION.—The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific use of a chemical substance or mixture, if the Administrator finds that—

"(A) the specific use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

"(B) compliance with the requirement, as applied with respect to the specific use, would significantly disrupt the national economy, national security, or critical infrastructure; or

"(C) the use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(2) EXEMPTION ANALYSIS AND STATEMENT.—In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

"(3) PERIOD OF EXEMPTION.—The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

"(4) CONDITIONS.—As part of a rule promulgated under this subsection, the Administrator shall include conditions, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the

conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(h) CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC.—

"(1) EXPEDITED ACTION.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose rules under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments—

"(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4, prior to the date of enactment of the Frank R.

Lautenberg Chemical Safety for the 21st Century Act; and

"(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

"(2) NO RISK EVALUATION REQUIRED.—The Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

"(3) FINAL RULE.—Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

"(4) SELECTING RESTRICTIONS.—In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.

"(5) RELATIONSHIP TO SUBSECTION (b).—If, at any time prior to the date that is 90 days after the date on which the Administrator proposes a rule under paragraph (1) with respect to a chemical substance, the Administrator makes a designation under subsection (b)(1)(B)(i), or receives a request under subsection (b)(4)(C)(ii) that meets the criteria prescribed by the Administrator in the rule promulgated under subsection (b)(4)(B), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

"(i) FINAL AGENCY ACTION.—Under this section and subject to section 18—

"(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order; and

"(2) a final rule promulgated under subsection (a)~~,~~ and ~~including~~ the associated determination by the Administrator under ~~that is based on a risk evaluation conducted in accordance with~~ subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

"(j) CHEMICAL SUBSTANCES CURRENTLY ASSESSED AS LOW-HAZARD.—Not later than one year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall publish a list of not fewer than 25 chemical substances, including uses of a chemical substance identified by the Administrator, that the Administrator has reason to conclude should not be high priorities for risk evaluation under this section because information demonstrates that such chemical substances do not pose a hazard to human health or the environment.

"(k) DEFINITION.—For the purposes of this Act, the term 'requirement' as used in this section shall not displace statutory or common law.".

SEC. 7. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

Commented [A17]: Looks like the comma should be retained and the "and" stricken

(1) in subsection (b)(1), by inserting "(as identified by the Administrator without consideration of costs or other nonrisk factors)" after "from the unreasonable risk"; and

(2) in subsection (f), by inserting ", without consideration of costs or other nonrisk factors" after "widespread injury to health or the environment".

[Page 56 – 73 (below)– remove all brackets]

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) IN GENERAL.—Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

~~(A) in paragraph (1) by striking "The Administrator shall promulgate" and inserting "Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate or revise";~~

(B) in paragraph (2), by striking the matter that follows subparagraph (G);

(C) in paragraph (3), by adding at the end the following:

"(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 10 years thereafter, the Administrator, after consultation

with the Administrator of the Small Business Administration, shall—

"(i) review the adequacy of the standards prescribed under subparagraph (B); and

"(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted."; and

(D) by adding at the end the following:

"(4) CONTENTS.—The rules promulgated pursuant to paragraph (1)—

"(A) may impose differing reporting and recordkeeping requirements on manufacturers and processors; and

"(B) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

"(5) ADMINISTRATION.—In carrying out this section, the Administrator shall, to the extent feasible—

"(A) not require reporting which is unnecessary or duplicative;

"(B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and

"(C) apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(6) NEGOTIATED RULEMAKING.—(A) The Administrator shall enter into a negotiated rulemaking pursuant to subchapter III of chapter 5 of title 5, United States Code, to develop and publish, not later than 2 years ?after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a proposed rule providing ~~for limiting reporting for any inorganic byproducts which are subsequently recycled, reused, or reprocessed, including by any other person~~ a proposed rule providing for limiting the reporting requirements, under this subsection, of manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed..

Commented [A18]: "a proposed rule providing" is repeated

"(B) Not later than 3 and one-half years after such date of enactment, the Administrator shall publish a final rule resulting from such negotiated rulemaking."; and

(2) in subsection (b), by adding at the end the following:

~~"(3) NOMENCLATURE.—~~

~~"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—~~

~~"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;~~

~~"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and~~

~~"(iii) treat all chemical substances described by the following category listings, when manufactured as described in such appendix, as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories:~~

~~"(I) Cement, Portland, chemicals, CAS No. 65997–15–1.~~

~~"(II) Cement, alumina, chemicals, CAS No. 65997–16–2.~~

~~"(III) Glass, oxide, chemicals, CAS No. 65997–17–3.~~

~~"(IV) Frits, chemicals, CAS No. 65997–18–4.~~

~~"(V) Steel manufacture, chemicals, CAS No. 65997–19–5.~~

~~"(VI) Ceramic materials and wares, chemicals, CAS No. 66402–68–4.~~

~~"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—~~

~~"(i) IN GENERAL.—The Administrator shall—~~

~~"(I) maintain the nomenclature conventions for chemical substances; and~~

~~"(II) develop new guidance that—~~

~~"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and~~

~~"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).~~

~~"(ii) MULTIPLE CAS NUMBERS.—For a chemical substance determined by the Administrator to appear multiple times on the list in paragraph (1) under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.~~

~~"(C) RELATIONSHIP TO SECTION 5.—~~

~~"(i) CHEMICAL SUBSTANCES DESCRIBED BY CATEGORIES. Notwithstanding subparagraph (A), a chemical substance that is described by a category listed in subparagraph (A)(iii) shall be subject to section 5 if the chemical substance is not included as an individual chemical substance on the list published under paragraph (1) as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.~~

~~"(ii) CHEMICAL SUBSTANCES GROUPED BY CAS NUMBER. Notwithstanding subparagraph (B), a chemical substance that is not included as an individual chemical substance on the list published under paragraph (1) as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act shall be subject to section 5.~~

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

(iii) treat the individual members of the categories of chemical substances identified by the Administrator as statutory mixtures, as defined in Inventory descriptions established by the Administrator, as being included on the list established under paragraph (1).

"(B)

MULTIPLE NOMENCLATURE LISTINGS.—

Following a request by a manufacturer or processor to review information reasonably available tofthe Administrator that demonstrates that a chemical substance appears multiple times on the list published under paragraph (1) under different CAS numbers, the Administrator may recognize the multiple listings as a single chemical substance.

Commented [A19]: "To the," not "tofthe"

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers, and may require processors, subject to the limitations under ~~subsection (a)(5)(A),~~ 5(a)(1)(A)(I) [?] to notify the Administrator, by not later than 180 days after the date on which the final rule is published in the Federal Register, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a non-

Commented [A20]: We had trouble identifying where in the bill this change should go, because the page and line numbers provided did not seem quite right. This was our best guess, but having tried it here, we note that it doesn't work. This is the provision the prevents manufacture of a new chemical without undertaking the PMN process. Since this provision (4)(A)(I) pertains only to chemicals already on the inventory, it's not clear how that reference would be relevant. So maybe we got the wrong spot.

exempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

"(iv) LIMITATION.—No chemical substance on the list published under paragraph (1) shall be removed from such list by reason of the implementation of this subparagraph, or be subject to section 5 by reason of a change to active status under paragraph (5)(B).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating a rule under subparagraph (A), the Administrator shall—

"(i) maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) require any manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential pursuant to section 14 to submit a notice under subparagraph (A) that includes such request;

"(iii) require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C); and

"(iv) move any active chemical substance for which no request was received to maintain an existing claim for protection

against disclosure of the specific chemical identity of the chemical substance as confidential from the confidential portion of the list published under paragraph (1) to the nonconfidential portion of that list.

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the list published under paragraph (1) that are asserted pursuant to subparagraph (B).

"(D) REQUIREMENTS OF REVIEW PLAN.—In establishing the review plan under subparagraph (C), the Administrator shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim, in accordance with section 14, unless the manufacturer or processor has substantiated the claim in a submission made to the Admin-

istrator during the 5-year period ending on the date of the request by the Administrator; and

"(ii) in accordance with section 14—

"(I) review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim qualifies for protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, approve in part and deny in part, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim

for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the claim, in which ~~case the Administrator shall ϕnot protect the information from disclosure;~~ case the Administrator shall promptly make the specific chemical identity available to the public; or

"(bb) the Administrator otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Administrator shall take the actions described in section 14(g)(2).

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of claims needing review and the available resources.

"(II) ANNUAL REVIEW GOAL AND RESULTS.—At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall keep designations of active substances and inactive substances on the list published under paragraph (1) current.

"(B) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive

substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the inactive substance as confidential, the person shall, consistent with the requirements of section 14—

"(I) in the notice submitted under clause (i), assert the claim; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific chemical identity of the chemical substance and approve, approve in part and deny in part, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific chemical identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the claim, in which ~~case the Administrator shall ϕnot protect the information from disclosure¿;~~ case the Administrator shall promptly make the specific chemical identity available to the public; or

"(bb) the Administrator otherwise becomes aware that the information does not qualify for

protection from disclosure, in which case the Administrator shall take øthe actions described in section 14(g)(2)¿; and

"(IV) pursuant to section 6(b), review the priority of the chemical substance as the Administrator determines to be necessary.

"(C) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 6(b).

"(7) PUBLIC INFORMATION.—Subject to this subsection ¢and section 14¿, the Administrator shall make available to the public—

"(A) each specific chemical identity on the nonconfidential portion of the list published under paragraph (1) along with the Administrator's designation of the chemical substance as an active or inactive substance;

"(B) the ¢unique identifier assigned under section 14,¿ accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

"(C) the specific chemical identity of any active substance for which—

"(i) a claim for protection against disclosure of the specific chemical identity of the active substance was not asserted, as required under this subsection or section 14;

"(ii) all claims for protection against disclosure of the specific chemical identity of the active substance have been denied by the Administrator; or

Commented [A21]: 1.The section already requires EPA to designate chemical substances as active and inactive. What is gained by this additional statement of the requirement? 2. Is there some reason this obligation to identify the substance as active or inactive applies only under (A), for non-confidential substances, and not under (B), for confidential substances?

"(iii) the time period for protection against disclosure of the specific chemical identity of the active substance has expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection or section 14 for protection from disclosure of a specific chemical identity of any active or inactive substance for which a notice is received under paragraph (4)(A)(i) or (5)(B)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers ø and processors, as applicable,¿ shall be required—

"(A) to certify that each notice or substantiation the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record ødocumenting compliance with the rule and supporting confidentiality claims¿ for a period of 5 years beginning on the last day of the submission period.".

[Page 56-73 (above), remove all brackets]

(b) MERCURY INVENTORY.—Section 8(b) of the Toxic Substances Control Act (15 U.S.C. 2607(b)) (as

amended by subsection (a)) is further amended by adding at the end the following:

"(10) MERCURY.—

"(A) DEFINITION OF MERCURY.—In this paragraph, notwithstanding section 3(2)(B), the term 'mercury' means—

"(i) elemental mercury; and

"(ii) a mercury compound.

"(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

"(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

"(i) identify any manufacturing processes or products that intentionally add mercury; and

"(ii) recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use.

"(D) REPORTING.—

"(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph (B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after the date of enactment of this paragraph.

"(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse and any applicable reporting requirements under the Solid Waste Disposal Act.

"(iii) EXEMPTION.—Clause (i) shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.".

[***Add back Definitions of "active" and "inactive"]

???

"(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(iii)INACTIVE SUBSTANCES.—TheAdministrator shall designate chemical substances for which no notices are re-ceived under clause (i) to be inactive substances on the list published under para-graph (1).

Commented [A22]: Conceptually ok

Commented [A23]: These provisions already appear on p 64. Perhaps the intent is to add the definitions from 8(f)(1) and (2) of senate bill and offer

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by inserting ", ~~without consideration of costs or other nonrisk factors,~~" after ~~"basis to conclude"; and~~ "has reasonable basis to conclude" and inserting "determines";

Commented [A24]: Garbled. Inserts two different standards.

(ii) ~~by inserting "under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator," after "health or the environment";~~ "or will present" after "presents"; and

Commented [A25]: Garbled

(iii) by inserting "without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use" after "or the environment";

Commented [A26]: Not clear where this goes.

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ", within the time period specified by the

Administrator in the report," after "issues an order"; and

(ii) in subparagraph (B), by inserting "responds within the time period specified by the Administrator in the report and" before "initiates, within 90";

(C) by redesignating paragraph (3) as paragraph (6); and

(D) by inserting after paragraph (2) the following:

"(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

"(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

"(B)(i) respond under paragraph (1) within the timeframe specified by the Administrator in the report; and

"(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

"(4) If an agency to which a report is submitted under paragraph (1) does not take the actions described in subparagraph (A) or (B) of paragraph (3), the Administrator shall—

"(A) if a risk evaluation for a chemical substance included in the report has not been completed under section 6(b), complete the risk evaluation;

"(B) if the Administrator has made a determination of unreasonable risk in accordance with

section 6(b)(4)(A), initiate action under section 6(a) with respect to the risk; or

"(C) take any action authorized or required under section 7, as ~~appropriate~~ applicable.

"(5) This subsection shall not relieve the Administrator of any obligation to complete a risk evaluation or take any required action under section 6(a) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).";

(2) in subsection (b)—

(A) by striking "The Administrator shall coordinate" and inserting "(1) The Administrator shall coordinate"; and

(B) by adding at the end the following:

"(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, to the extent practicable based on information reasonably available to the Administrator, the relative aspect of the risks~~~~ and a comparison of the estimated costs and efficiencies

of the action to be taken under this title and an action to be taken under such other law to protect against such risk."; and

(3) by adding at the end the following:

"(e) EXPOSURE INFORMATION.—In addition to the requirements of subsection (a), if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

Commented [A27]: This wording is improved, but it is still not clear what 'the relative aspects of the risk" means. Relative to what?

Section 12 - Exports

* 12(a)(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator determines, without consideration of costs or other non-risk factors, that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States, under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator. The Administrator may require, under section 4, the development of new information for any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining, without consideration of costs or other non-risk factors, whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.-

Commented [A28]: We are assuming this is intended as a replacement for TSCA 12(a)(2).

Commented [A29]: The beginning of the sentence says "will present".

SEC. 10. EXPORTS OF ELEMENTAL MERCURY. [CLOSED]

(a) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—Section 12(c) of the Toxic Substances Control Act (15 U.S.C. 2611(c)) is amended—

(1) in the subsection heading, by inserting "AND MERCURY COMPOUNDS" after "MERCURY";

and

(2) by adding at the end the following:

"(7) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—

"(A) IN GENERAL.—Effective January 1, 2020, the export of the following mercury compounds is prohibited:

"(i) Mercury (I) chloride or calomel.

"(ii) Mercury (II) oxide.

"(iii) Mercury (II) sulfate.

"(iv) Mercury (II) nitrate.

"(v) Cinnabar or mercury sulphide.

"(vi) Any mercury compound that the Administrator adds to the list published under subparagraph (B) by rule, on determining that exporting that mercury compound for the purpose of regenerating elemental mercury is technically feasible.

"(B) PUBLICATION.—Not later than 90 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and as appropriate thereafter, the Administrator shall publish in the Federal Register a list of the mercury compounds that are prohibited from export under this paragraph.

"(C) PETITION.—Any person may petition the Administrator to add a mercury compound to the list published under subparagraph (B).

"(D) ENVIRONMENTALLY SOUND DISPOSAL.—This paragraph does not prohibit the export of mercury compounds on the list published under subparagraph (B) to member countries of the Organization for Economic Cooperation and Development for environmentally sound disposal, on the condition that no mercury or mercury compounds so exported are to be recovered, recycled, or reclaimed for use, or directly reused, after such export.

"(E) REPORT.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall evaluate any exports of mercury compounds on the list published under subparagraph (B) for disposal that occurred after such date of enactment and shall submit to Congress a report that—

"(i) describes volumes and sources of mercury compounds on the list published under subparagraph (B) exported for disposal;

"(ii) identifies receiving countries of such exports;

"(iii) describes methods of disposal used after such export;

"(iv) identifies issues, if any, presented by the export of mercury compounds on the list published under subparagraph (B);

"(v) includes an evaluation of management options in the United States for mercury compounds on the list published under subparagraph (B), if any, that are commercially available and comparable in cost and efficacy to methods being utilized in such receiving countries; and

"(vi) makes a recommendation regarding whether Congress should further limit or prohibit the export of mercury compounds on the list published under subparagraph (B) for disposal.

"(F) EFFECT ON OTHER LAW.—Nothing in this paragraph shall be construed to affect the authority of the Administrator under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).".

(b) TEMPORARY GENERATOR ACCUMULATION.—Section 5 of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f) is amended—

(1) in subsection (a)(2), by striking "2013" and inserting "2019";

(2) in subsection (b)—

(A) in paragraph (1)—

(i) by redesignating subparagraphs (A), (B), and (C), as clauses (i), (ii), and (iii), respectively and indenting appropriately;

(ii) in the first sentence, by striking "After consultation" and inserting the following:

"(A) ASSESSMENT AND COLLECTION.—After consultation";

(iii) in the second sentence, by striking "The amount of such fees" and inserting the following:

"(B) AMOUNT.—The amount of the fees described in subparagraph (A)";

(iv) in subparagraph (B) (as so designated)—

(I) in clause (i) (as so redesignated), by striking "publically avail-

able not later than October 1, 2012" and inserting "publicly available not later than October 1, 2018";

(II) in clause (ii) (as so redesignated), by striking "and";

(III) in clause (iii) (as so redesignated), by striking the period at the end and inserting ", subject to clause (iv); and"; and

(IV) by adding at the end the following:

"(iv) for generators temporarily accumulating elemental mercury in a facility subject to subparagraphs (B) and (D)(iv) of subsection (g)(2) if the facility designated in subsection (a) is not operational by January 1, 2019, shall be adjusted to subtract the cost of the temporary accumulation during the period in which the facility designated under subsection (a) is not operational."; and

(v) by adding at the end the following:

"(C) CONVEYANCE OF TITLE AND PERMITTING.—If the facility designated in subsection

(a) is not operational by January 1, 2020, the Secretary—

"(i) shall immediately accept the conveyance of title to all elemental mercury that has accumulated in facilities in accordance with subsection (g)(2)(D), before January 1, 2020, and deliver the accumulated mercury to the facility designated under subsection (a) on the date on which the facility becomes operational;

"(ii) shall pay any applicable Federal permitting costs, including the costs for permits issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)); and

"(iii) shall store, or pay the cost of storage of, until the time at which a facility designated in subsection (a) is operational, accumulated mercury to which the Secretary has title under this subparagraph in a facility that has been issued a permit under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)).";

and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(C)" and inserting "paragraph (1)(B)(iii)"; and

(3) in subsection (g)(2)—

(A) in the undesignated material at the end, by striking "This subparagraph" and inserting the following:

"(C) Subparagraph (B)";

(B) in subparagraph (C) (as designated by subparagraph (A)), by inserting "of that subparagraph" before the period at the end; and

(C) by adding at the end the following:

"(D) A generator producing elemental mercury incidentally from the beneficiation or processing of ore or related pollution control activities may accumulate the mercury produced onsite that is destined for a facility designated by the Secretary under subsection (a) for more than 90 days without a permit issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)), and shall not be subject to the storage prohibition of section 3004(j) of that Act (42 U.S.C. 6924(j)), if—

"(i) the Secretary is unable to accept the mercury at a facility designated by the

Secretary under subsection (a) for reasons beyond the control of the generator;

"(ii) the generator certifies in writing to the Secretary that the generator will ship the mercury to a designated facility when the Secretary is able to accept the mercury;

"(iii) the generator certifies in writing to the Secretary that the generator is storing only mercury the generator has produced or recovered onsite and will not sell, or otherwise place into commerce, the mercury; and

"(iv) the generator has obtained an identification number under section 262.12 of title 40, Code of Federal Regulations, and complies with the requirements described in paragraphs (1) through (4) of section 262.34(a) of title 40, Code of Federal Regulations (as in effect on the date of enactment of this subparagraph).

"(E) MANAGEMENT STANDARDS FOR TEMPORARY STORAGE.—Not later than January 1, 2017, the Secretary, after consultation with the Administrator of the Environmental Protection

Agency and State agencies in affected States, shall develop and make available guidance that establishes procedures and standards for the management and short-term storage of elemental mercury at a generator covered under subparagraph (D), including requirements to ensure appropriate use of flasks or other suitable containers. Such procedures and standards shall be protective of human health and the environment and shall ensure that the elemental mercury is stored in a safe, secure, and effective manner. A generator may accumulate mercury in accordance with subparagraph (D) immediately upon enactment of this subparagraph, and notwithstanding that guidance called for by this paragraph has not been developed or made available.".

(c) INTERIM STATUS.—Section 5(d)(1) of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is amended—

(1) in the fourth sentence, by striking "in existence on or before January 1, 2013,"; and

(2) in the last sentence, by striking "January 1, 2015" and inserting "January 1, 2020".

SEC. 11. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) IN GENERAL.—Except as provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (c) are met.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

"(b) INFORMATION NOT PROTECTED FROM DISCLOSURE.—

¢the relationship among these paragraphs is not entirely clear¿

~~"(1) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Subsection (a) does not prohibit the disclosure of information that is not~~

~~protected from disclosure under this section on the basis that such information contains information described in subsection (a), subject to the condition that the Administrator shall protect from disclosure the information described in subsection (a) in disclosing the information that is not protected from disclosure.~~

"(~~2~~ 1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—Subsection (a) does not prohibit the disclosure of—

"(A) any health and safety study which is submitted under this Act with respect to—

"(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or

"(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5; and

"(B) any information reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the ¢release / *disclosure?*¿ [Senate raises question again] of any information, including formulas (including molecular structures) of a chemical substance or mixture, that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

"(~~3~~ 2)OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—Subsection (a) does not prohibit the disclosure of—

"(A) a risk evaluation published under section 6(b);

"(B) any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges; or

"(C) a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or

industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(3) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Information that is protected from disclosure under this section and which is mixed with information that is not protectable from disclosure under this section does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protectable from disclosure.

"(4) BANS AND PHASE-OUTS.—

"(A) IN GENERAL.—If the Administrator promulgates a rule pursuant to section 6(a) that establishes a complete or partial ban or phase-out of a chemical substance or mixture, the protection from disclosure of any information under this section with respect to the chemical substance or mixture shall be presumed to no longer apply, subject to subsection (g)(1)(E) and subparagraphs (B) and (C) of this paragraph.

"(B) LIMITATIONS.—

"(i) CRITICAL USE.—In the case of a chemical substance or mixture for which a specific ~~condition of~~ use is subject to an exemption pursuant to section 6(g), if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture,

the presumption against protection under such subparagraph shall only apply to information that relates solely to any ~~condi-~~

~~tions of~~ use of the chemical substance or mixture to which the exemption does not apply.

"(ii) EXPORT.—In the case of a chemical substance or mixture for which there is manufacture, processing, or distribution in commerce that meets the conditions of section 12(a)(1), if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any other manufacture, processing, or distribution in commerce for the use or uses subject to the ban or phase-out of the chemical substance or mixture, unless the Administrator makes the determination in section 12(a)(2).

"(iii) PARTIAL BANS AND PHASE-OUTS.—In the case of a chemical substance or mixture for which the Administrator establishes a ~~partial~~ ban or phase-out described in subparagraph (A) with respect to a specific condition of use of the chemical substance or mixture, the pre-

sumption against protection under such subparagraph shall only apply to information that relates solely to the condition of use of the chemical substance or mixture for which the ban or phase-out is established.

"(C) REQUEST FOR NONDISCLOSURE.—

"(i) IN GENERAL.—A manufacturer or processor of a chemical substance or mixture subject to a ban or phase-out described in this paragraph may submit to the Administrator, within 30 days of receiving a notification under subsection (g)(2)(A), a request, including documentation supporting such request, that some or all of the information to which the notice applies should not be disclosed or that its disclosure should be delayed, and the Administrator shall review the request under subsection (g)(1)(E).

"(ii) EFFECT OF NO REQUEST OR DENIAL.—If no request for nondisclosure or delay is submitted to the Administrator under this subparagraph, or the Administrator denies such a request under sub-

section (g)(1)(A), the Administrator shall, as practicable, promptly make the information public ~~the information shall not be protected from disclosure under this section~~.

"(5) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information reported to or otherwise obtained by the Administrator under this Act that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(c) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect from disclosure any information that person submits under this Act (including information described in paragraph (2)) shall assert to the Administrator a claim for protection from disclosure concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) ADDITIONAL REQUIREMENTS FOR CLAIMS REGARDING CHEMICAL IDENTITY INFORMATION.—In the case of a claim under subparagraph (A) for protection from disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall—

"(i) be consistent with guidance developed by the Administrator under paragraph (4)(A); and

"(ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are claimed as confidential; and

"(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

"(2) INFORMATION GENERALLY NOT SUBJECT TO SUBSTANTIATION REQUIREMENTS.—The following information shall not be subject to substantiation requirements under paragraph (3):

"(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(B) Marketing and sales information.

"(C) Information identifying a supplier or customer.

"(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

"(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

"(F) Specific production or import volumes of the manufacturer or processor.

"(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 5.

"(3) SUBSTANTIATION REQUIREMENTS.—Except for information described in paragraph (2), a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Adminis-

trator has promulgated or may promulgate pursuant to this section.

"(4) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection from disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (d).

"(5) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B), and any information required to substantiate a claim submitted pursuant to paragraph (3), are true and correct.

"(d) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Information described in subsection (a)—

"(1) shall be disclosed to an officer or employee of the United States—

"(A) in connection with the official duties of that person under any Federal law for the protection of health or the environment; or

"(B) for a specific Federal law enforcement purpose;

"(2) shall be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines, that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use;

"(4) shall be disclosed to a State, political subdivision of a State, or tribal government, on written request, for the purpose of administration or enforcement of a law, if such entity has 1 or more applicable agreements with the Administrator that are consistent with the guidance developed under sub-

section (c)(4)(B) and ensure that the entity will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information;

"(5) shall be disclosed to a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation if such person provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement are consistent with the guidance developed under subsection (c)(4)(B);

"(B) the statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

"(C) the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person who has a claim under this section with respect to the information, except that nothing in this title prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed in the event of an emergency to a treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder (including any individual duly authorized by a Federal agency, State, political subdivision of a State, or

tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) if such person requests the information, subject to the conditions that such person shall—

"(A) have a reasonable basis to suspect that—

"(i) a medical, public health, or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

"(B) if requested by a person who has a claim with respect to the information under this section—

"(i) provide a written statement of need and agree to sign a confidentiality

agreement, as described in paragraph (5); and

"(ii) submit to the Administrator such statement of need and confidentiality agreement as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding; and

"(8) shall be disclosed if the information is required to be made public under any other provision of Federal law.

"(e) DURATION OF PROTECTION FROM DISCLOSURE.—

"(1) IN GENERAL.—The Administrator shall protect from disclosure information ~~described in subsection (a)~~ that meets the requirements of subsection (a) and the applicable requirements of subsection (c)—

"(A) in the case of information described in subsection (c)(2), until such time as—

"(i) the person that asserted the claim notifies the Administrator that the person

is withdrawing the claim, in which case the ~~information shall not be protected from disclosure under this section; or~~ Administrator shall, as practicable, promptly make the information available to the public; or

"(ii) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsection (f) and (g); and

~~subsection¢s (f) and¿ ¢*what would happen under (f)? (f) appears to not apply to (c)(2) information. strike?*¿ (g);~~ and

"(B) ¢*subject to paragraph (2), subsection (f)(3), and section 8(b),*¿ ¢*link is needed to prevent conflicting deadlines*¿ in the case of information other than information described in subsection (c)(2)—

"(i) for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator; or

"(ii) ~~¢*if applicable before the expiration of such 10-year period,*¿ ¢*since this is an 'or' list and (i) has a set period, need a rule to decide which clause applies*¿~~ if applicable

before the expiration of such 10-year period, until such time as—

"(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, ~~in which case the information shall not be protected from disclosure under this section~~; in which case the Administrator shall, as practicable promptly make the information available to the public; or

"(II) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g).

"(2) EXTENSIONS.—

"(A) IN GENERAL.—In the case of information other than information described in subsection (c)(2), not later than the date that is 60 days before the expiration of the period described in paragraph (1)(B)(i), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(B) REQUEST.—

"(i) IN GENERAL.—Not later than the date that is 30 days before the expiration

of the period described in paragraph (1)(B)(i), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (c)(3), the need to extend the period.

"(ii) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in paragraph (1)(B)(i), the Administrator shall, in accordance with subsection (g)(1)—

"(I) review the request submitted under clause (i);

"(II) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant requirements of this section; and

"(III)(aa) grant an extension of 10 years; or

"(bb) deny the request.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under this paragraph, if

the Administrator determines that the relevant request under subparagraph (B)(i)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(f) REVIEW AND RESUBSTANTIATION.—

¿is anything in this subsection intended to apply to (c)(2) information?¿ [SENATE: yes, (f) does apply to (c)(2)]

"(1) DISCRETION OF ADMINISTRATOR.—The Administrator may require any person that has claimed protection for information from disclosure under this section, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to reassert and substantiate or resubstantiate the claim in accordance with this section ~~*¿subsection (c) / this section?¿*~~

~~*¿see below¿*~~

"(A) after the chemical substance is designated as a high-priority substance under section 6(b);

"(B) for any chemical substance designated as an active substance under section 8(b)(5)(B)(iii); or

"(C) if the Administrator determines that disclosure of certain information currently protected from disclosure would be important to assist the Administrator in conducting risk evaluations or promulgating rules under section 6.

"(2) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information from disclosure under this section and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to reassert and substantiate or resubstantiate the claim in accordance with ϕthis section / *subsection (c)?¿ ϕsee above¿*—

"(A) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(B) if the Administrator has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section; or

"(C) for any chemical substance the Administrator determines under ~~(in accordance with / under?)~~ section 6(b)(4)(A) presents an unreasonable risk of injury to health or the environment.

"(3) PERIOD OF PROTECTION.—If the Administrator requires a person to reassert and substantiate or resubstantiate a claim under this subsection, and determines that the claim continues to meet the relevant requirements of this section, the Administrator shall protect the information subject to the claim from disclosure for a period of 10 years from the date of such determination, subject to any subsequent requirement by the Administrator under this subsection.

"(g) DUTIES OF ADMINISTRATOR.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except for claims regarding information described in subsection (c)(2), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (c), and not later than 30 days after the receipt of a request for extension of a claim under subsection (e) or a request under subsection (b)(4)(C), review

and approve, approve in part and deny in part, or deny the claim or request.

"(B) REASONS FOR DENIAL.—If the Administrator denies or denies in part a claim or request under subparagraph (A) the Administrator shall provide to the person that asserted the claim or submitted the request a written statement of the reasons for the denial or denial in part of the claim or request.

"(C) SUBSETS.—The Administrator shall—

"(i) except with respect to information described in subsection (c)(2)(G), review all claims or requests under this section for the protection from disclosure of the specific chemical identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection from disclosure under this section.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection from disclosure or extension under this section shall

not have the effect of denying or eliminating a claim or request for protection from disclosure.

"(E) DETERMINATION OF REQUESTS UNDER SUBSECTION (b)(4)(C).—With respect to a request submitted under subsection (b)(4)(C), the Administrator shall, with the objective of ensuring that information relevant to the protection of health and the environment is disclosed to the extent practicable, determine whether the documentation provided by the person rebuts what shall be the presumption of the Administrator that the public interest in the disclosure of the information outweighs the public or proprietary interest in maintaining the protection for all or a portion of the information that the person has requested not be disclosed or for which disclosure be delayed.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (b), (d), and (e), if the Administrator denies or denies in part a claim or request under paragraph (1), concludes, in accordance with this section, that the information does not qualify for protection from disclosure, intends to disclose information

pursuant to subsection (d), or promulgates a rule under section 6(a) establishing a ban or phase-out with respect to a chemical substance or mixture, the Administrator shall notify, in writing, the person that asserted the claim or submitted the request of the intent of the Administrator to disclose the information or not protect the information from disclosure under this section. The notice shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means that allows verification of the fact and date of receipt.

"(B) DISCLOSURE OF INFORMATION.—Except as provided in subparagraph (C), the Administrator shall not disclose information under this subsection until the date that is 30 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A).

"(C) EXCEPTIONS.—

"(i) FIFTEEN DAY NOTIFICATION.—For information the Administrator intends to disclose under subsections (d)(3), (d)(4), (d)(5), and (j), the Administrator shall not disclose the information until the date that

is 15 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A), except that, with respect to information to be disclosed under subsection (d)(3), if the Administrator determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information the Administrator intends to disclose under paragraph (6) of subsection (d), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of information under paragraphs (1), (2), (7), or (8) of subsection (d); or

"(II) for the disclosure of information for which—

"(aa) the Administrator has provided to the person that asserted the claim a notice under subsection (e)(2)(A); and

"(bb) such person does not submit to the Administrator a request under subsection (e)(2)(B) on or before the deadline established in subsection (e)(2)(B)(i).

"(D) APPEALS.—

"(i) ACTION TO RESTRAIN DISCLOSURE.—If a person receives a notification under this paragraph and believes the information is protected from disclosure under this section, before the date on which the information is to be disclosed pursuant to subparagraph (B) or (C) the person may bring an action to restrain disclosure of the information in—

"(I) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(II) the United States District Court for the District of Columbia.

"(ii) NO DISCLOSURE.—

"(I) IN GENERAL.—The Administrator shall not disclose information that is the subject of an appeal under this paragraph before the date on which the applicable court rules on an action under clause (i).

"(II) EXCEPTION.—Subclause (I) shall not apply to disclosure of information described under subsections (d)(4) and (j).

"(3) REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).

"(4) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical iden-

tity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to a chemical substance included on the list published under subparagraph (B) while the specific chemical identity of the chemical substance is protected from disclosure under this section identifies the chemical substance using the unique identifier and is made public; and

"(D) for each claim for protection of a specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the person who asserted the

claim, and for which the Administrator has used a unique identifier assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such information to the extent practicable.

"(h) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

"(1) INDIVIDUALS SUBJECT TO PENALTY.—

"(A) IN GENERAL.—Subject to subparagraph (C) and paragraph (2), an individual described in subparagraph (B) shall be fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—An individual referred to in subparagraph (A) is an individual who—

"(i) pursuant to this section, obtained possession of, or has access to, information protected from disclosure under this section; and

"(ii) knowing that the information is protected from disclosure under this section, willfully discloses the information in

any manner to any person not entitled to receive that information.

"(C) EXCEPTION.—This paragraph shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information obtained under paragraph (5) or (6) of subsection (d) to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, or making known of or making available information reported to or otherwise obtained by the Administrator under this Act.

"(i) APPLICABILITY.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information reported to or

otherwise obtained by the Administrator under this Act prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or re-substantiation requirements, with respect to the protection of information described in subsection (a), under this Act that are more extensive than those required under this section.

"(2) ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or re-substantiation of, or approving, approving in part, or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(j) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon writ-

ten request of any duly authorized committee of the Congress, to such committee.".

SEC. 12. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1), by striking "$25,000" and inserting "$37,500"; and

(2) in subsection (b)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person";

(B) by striking "$25,000" and inserting "$50,000"; and

(C) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person who knowingly and willfully violates any provision of section 15 or 409, and who knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—Notwithstanding the penalties described in subparagraph (A), an organization that commits a knowing violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(C) INCORPORATION OF CORRESPONDING PROVISIONS.—Subparagraphs (B) through (F) of section 113(c)(5) of the Clean Air Act (42 U.S.C. 7413(c)(5)(B)–(F)) shall apply to the prosecution of a violation under this paragraph.".

SEC. 13. STATE-FEDERAL RELATIONSHIP.

¿To be determined¿

SEC. 14. JUDICIAL REVIEW.

Section 19(a) of the Toxic Substances Control Act (15 U.S.C. 2618(a)) is amended—

(1) in paragraph (1), by adding at the end the following:

"(C)(i) Not later than 60 days after the publication of a designation under section 6(b)(1)(B)(ii), any person may commence a civil action to challenge the designation.

"(ii) The United States Court of Appeals for the District of Columbia Circuit shall have exclusive

jurisdiction over a civil action filed under this subparagraph."; and

(2) by striking paragraph (3).

øSEC. 15. CITIZENS' CIVIL ACTIONS.

Section 20(b) of the Toxic Substances Control Act (15 U.S.C. 2619(b)) is amended—¿

ø(1) in paragraph (1)(B), by striking "or" at the end; and¿

ø(2) in paragraph (2), by striking the period at the end and inserting the following:¿ ", except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to øsection 18(f)(3)(B)¿; or

ø"(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to øsection 18(f)(3)(B)¿, after the date that is 60 days after the deadline specified in øsection 18(f)(3)(B)¿.".¿

SEC. 16. CITIZENS' PETITIONS.

Section 21(b)(4) of the Toxic Substances Control Act (15 U.S.C. 2620(b)(4)) is amended by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) respecting a petition to ini-

tiate a proceeding to issue a rule under section 4, 5, 6, or 8 or issue an order under section 4 or 5(e) or (f), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information is needed for a purpose identified in section 4(a);

"(bb) in the case of a petition to issue an order under section 5(f), the chemical substance may present an unreasonable risk in accordance with section 5(a)(3)(A) ϕ*clause (i) covers rules under section 5 and orders under section 5(e) and (f), but this only*

Commented [A30]: This litany in the judicial review paragraph of sec 21 does not align with sec 21(a), unamended, which authorizes petitions only for rules under sections 4, 6 and 8 and orders under 5(e) and 6(b)(2) (the latter of which has been stricken in this version of the bill). The judicial review provision adds section 5 rules and 5(f) orders, and does not account for 6(b)(2). The most straightforward fix would probably be to simply drop the reference to 6(b)(2) in 21(a) and then have the citations in this provision match the citations in (a).

If that is done, though, one issue still remains. Section 21(a) and this provision (B)(i) allow petitions for 5(e) orders and judicial review of denials, but (B)(ii) provides no standard for review of denials of petitions for section 5(e) orders. Either 5(e) should be dropped from section 21 entirely, or a standard for judicial review should be added. There is a good rationale for dropping it (which would also be the simplest solution). Under current TSCA, presumably a *citizen* would petition for a sec 5(e) order, in order to block manufacture or processing. (EPA has never received such a petition as far as we know, and it would be unlikely that EPA could receive and process a petition within the section 5 review period.) However, under the revised section 5, it would more likely be the *submitter* who wants a 5(e) order, to enable manufacture or processing to commence, and the submitter would have a more powerful remedy than a sec 21 petition: a suit under TSCA section 20 to force EPA to perform the non-discretionary duty to take action within the review period, as required by section 5. So, the inclusion of 5(e) in section 21 seems like a vestige.

speaks of orders under 5(e). Is that intentional?¿; [SENATE: yes intentional]

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(a), the chemical substance presents an unreasonable risk in accordance with section 6(b)(4)(A); or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance does not present an unreasonable risk of injury to health or the environment, as determined without consideration of costs or other nonrisk factors, under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator.

"(II) DEFERMENT.—The court in a de novo proceeding under this subpara-

Commented [A31]: Per comment above, section 21(a) does not provide for petitions for 5(f) rules. And, for the same reasons expressed in that comment, such a petition opportunity may not make sense.

graph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 17. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 18. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (b)(1)—

(A) by striking "of a reasonable fee";

(B) by striking "data under section 4 or 5 to defray the cost of administering this Act"

and inserting "information under section 4 or a notice or other information to be reviewed by the Administrator under section 5, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b), of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, including contractor costs incurred by the Administrator";

(C) by striking "Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100."; and

(D) by striking "submit the data and the cost to the Administrator of reviewing such data" and inserting "pay ~~such~~ the fee and the cost to the Administrator of carrying out the activities described in this paragraph";

(2) by adding at the end of subsection (b) the following:

"(3) FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the 'Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

"(B) COLLECTION AND DEPOSIT OF FEES.—The Administrator shall collect the fees described in this subsection and deposit ~~those~~ the fees in the Fund.

"(C) CREDITING AND AVAILABILITY OF FEES.—On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated ~~to pay or recover the costs incurred by the Environmental Protection Agency in carrying out the provisions of this title for which the fees are collected under~~ for use in defraying the costs of the activities described in paragraph (1).

"(D) USE OF FUNDS BY ADMINISTRATOR.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in ~~subsection (b)(1)~~ paragraph (1).

"(E) ACCOUNTING AND AUDITING.—

"(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

"(ii) AUDITING.—

"(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

"(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

"(aa) the fees collected and amounts disbursed under this subsection;

"(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this title for which the fees may be used; and

"(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(4)(C)(ii).

"(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

"(4) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—

"(i) the lower of—

"(I) 25 percent of the costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than the costs to conduct and complete risk evaluations under section 6(b); or

"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

"(ii) the full costs and the 50-percent portion of the costs of risk evaluations specified in subparagraph (D)~~(ii);~~

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and proc-

essors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B)—

"(i) except as provided in clause (ii), for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section ~~6(b)(4)(A)(ii),~~ 6(b)(4)(C)(ii), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 6(b);

"(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section ~~6(b)(4)(A)(ii),~~ 6(b)(4)(C)(ii), and which are included in the 2014 update of the TSCA Work Plan for Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the ~~annual~~ costs to the Administrator of conducting the risk evaluation under section 6(b); and

"(iii) ~~fees collected pursuant to clauses (i) and (ii) shall be applied by the Administrator only to defray the costs described in clauses (i) and (ii);~~ apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses"

"(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet

with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App. or Subchapter II of Chapter 5 of title 5, United States Code) [Senate: Ensures that the rulemaking will not be considered a negotiated rulemaking.] is applicable with respect to such meetings;

Commented [A32]: Shouldn't this be III?

"(F) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray—

"(i) approximately but not more than 25 percent of the annual costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than the costs to conduct and complete risk evaluations requested under section ~~6(b)(4)(A)(ii)~~

6(b)(4)(C)(ii);

and

"(ii) the full annual costs and the 50-percent portion of the annual costs of risk evaluations specified in subparagraph (D); and

"(G) if a notice submitted under section 5 is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for that program project for fiscal year 2014.

"(6) TERMINATION.—The authority provided by this subsection shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress."; and

(3) by adding at the end the following:

"(h) SCIENTIFIC STANDARDS.—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall

use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

"(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

"(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

"(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

"(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

"(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

"(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.

"(j) AVAILABILITY OF INFORMATION.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this title;

"(2) any information required to be provided to the Administrator under section 4;

"(3) a nontechnical summary of each risk evaluation conducted under section 6(b); and

"(4) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with ~~and~~ the results of those studies.

"(k) REASONABLY AVAILABLE INFORMATION.—In carrying out sections 4, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

"(l) POLICIES, PROCEDURES, AND GUIDANCE.—

"(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of the Frank R. Lauten-

berg Chemical Safety for the 21st Century Act, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(2) REVIEW.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this title; and

"(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

"(3) Testing of Chemical Substances and Mixtures.—The policies, procedures, and guidance established under paragraph (1) applicable to testing of chemical substances and mixtures shall —

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not

interpret the lack of exposure information as a lack of exposure or exposure potential; and

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations.

Commented [A33]: Should be subpopulations

"(~~3~~4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the

Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6 ~~as in effect before such date of enactment.~~

"(45) GUIDANCE.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(6) NOTICE OF EXISTING INFORMATION.—

(A) IN GENERAL.—The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in risk evaluations with the objective of increasing the efficiency of the risk evaluations.

(B) INCLUSION OF INFORMATION.—Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.

Commented [A34]: Inlcuded where? (A) already provides for incorporation into risk evaluations. Also, A and B present two different standards for incorporating/including the information described in A.

"(m) REPORT TO CONGRESS.—

"(1) INITIAL REPORT.—Not later than 6 months after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations

of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

"(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under ~~ø~~~~subparagraphs (A)(i) and (B) of section 6(b)(3) / not sure what this is supposed to refer to¿~~ 6(b)(4)(C)(i) and(ii) and the resources necessary to ~~initiate~~ be conducting the minimum number of risk evaluations required under ~~ø~~~~section 6(b)(7) / subsection (b)(2) has the only 'minimum requirements' left in section 6. Is that what this should refer to?¿~~ section 6(b)(2);

"(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 6(b)(4)(A)(ii), the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

"(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

"(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 6(b).

"(2) SUBSEQUENT REPORTS.—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

"(n) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall publish an annual plan that—

"(1) identifies the chemical substances for which risk evaluations are expected to be completed that year and the resources necessary for their completion;

"(2) describes the status of each risk evaluation that has been initiated but not yet completed; and

"(3) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

"(o) CONSULTATION WITH SCIENCE ADVISORY COMMITTEE ON CHEMICALS.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the

Administrator shall establish an advisory committee, to be known as the Science Advisory Committee on Chemicals (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(p) PRIOR ACTIONS.—

"(1) RULES, ORDERS, AND EXEMPTIONS.—Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(2) PRIOR-INITIATED EVALUATIONS.—Nothing in ~~the Frank R. Lautenberg Chemical Safety for the 21st Century Act~~ this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator under ~~this section or section 6~~ the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(3) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES, PROCEDURES, AND GUIDANCE.—Nothing in the ~~Frank R. Lautenberg Chemical Safety for the 21st Century Act~~ this Act requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule under this Act solely because the action was completed prior to the development of a policy, procedure, or guidance ~~under subsection (l)~~. under the Frank R. Lautenberg Chemical Safety for the

21st Century Act.".

SEC. 19. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended by striking subsections (c) and (d).

SEC. 20. CONFORMING AMENDMENTS.

(a) TABLE OF CONTENTS.—The table of contents in section 1 of the Toxic Substances Control Act is amended—

(1) by striking the item relating to section 6 and inserting the following:

"Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.";

(2) by striking the item relating to section 10 and inserting the following:

"Sec. 10. Research, development, collection, dissemination, and utilization of information.";

(3) by striking the item relating to section 14 and inserting the following:

"Sec. 14. Confidential information."; and

(4) by striking the item relating to section 25.

(b) SECTION 2.—Section 2(b)(1) of the Toxic Substances Control Act (15 U.S.C. 2601(b)(1)) is amended by striking "data" both places it appears and inserting "information".

(c) SECTION 3.—Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) in paragraph (8) (as redesignated by section 3 of this Act), by striking "data" and inserting "information"; and

(2) in paragraph (15) (as redesignated by section 3 of this Act)—

(A) by striking "standards" and inserting "protocols and methodologies";

(B) by striking "test data" both places it appears and inserting "information"; and

(C) by striking "data" each place it appears and inserting "information".

(d) SECTION 4.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking "rule" each place it appears and inserting "rule, order, or consent agreement";

(B) in paragraph (2)(B), by striking "rules" and inserting "rules, orders, and consent agreements"; and

(C) in paragraph (4)—

(i) by striking "rule under subsection (a)" each place it appears and inserting "rule, order, or consent agreement under subsection (a)";

(ii) by striking "repeals the rule" each place it appears and inserting "repeals the rule or order or modifies the consent agreement to terminate the requirement"; and

(iii) by striking "repeals the application of the rule" and inserting "repeals or modifies the application of the rule, order, or consent agreement";

(2) in subsection (c)—

(A) in paragraph (1), by striking "rule" and inserting "rule or order";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "a rule under subsection (a) or for which data is being developed pursuant to such a rule" and inserting "a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement";

(ii) in subparagraph (B), by striking "such rule or which is being developed pursuant to such rule" and inserting "such rule, order, or consent agreement or which

is being developed pursuant to such rule, order, or consent agreement"; and

(iii) in the matter following subparagraph (B), by striking "the rule" and inserting "the rule or order";

(C) in paragraph (3)(B)(i), by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(D) in paragraph (4)—

(i) by striking "rule promulgated" each place it appears and inserting "rule, order, or consent agreement";

(ii) by striking "such rule" each place it appears and inserting "such rule, order, or consent agreement"; and

(iii) in subparagraph (B), by striking "the rule" and inserting "the rule, order, or consent agreement";

(3) in subsection (d), by striking "rule" and inserting "rule, order, or consent agreement"; and

(4) in subsection (g), by striking "rule" and inserting "rule, order, or consent agreement".

(e) SECTION 5.—Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (b)—

(A) in paragraph (1)(A)—

(i) by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(ii) by striking "such rule" and inserting "such rule, order, or consent agreement";

(B) in paragraph (1)(B)—

(i) by striking "rule promulgated" and inserting "rule or order"; and

(ii) by striking "the date of the submission in accordance with such rule" and inserting "the required date of submission"; and

(C) in paragraph (2)(A)(ii), by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(2) in subsection (d)(2)(C), by striking "rule" and inserting "rule, order, or consent agreement".

(f) SECTION 7.—Section 7(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2606(a)(1)) is amended, in the matter following subparagraph (C), by striking "a rule under section 4, 5, 6, or title IV or an order under section 5 or title IV" and inserting "øa determination under section 5 or 6,¿ a rule under section 4, 5, or 6 or

title IV, an order under section 4 or 5 or title IV or 6(i), or a consent agreement under section 4". ϕ*does this need to pull in 6(i) orders?*¿YES 6(i)

(g) SECTION 8.—Section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607(a)) is amended—

(1) in paragraph (2)(E), by striking "data" and inserting "information"; and

(2) in paragraph (3)(A)(ii)(I), by striking "or an order in effect under section 5(e)" and inserting ", an order in effect under section 4 or 5(e), or a consent agreement under section 4". ϕ*does this need to pull in 6(i) orders?*¿ NO 6(i)

(h) SECTION 9.—Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

ϕ(1) in subsection (a), by striking "section 6" each place it appears and inserting "section 6(a)"; and¿

(2) in subsection (d), by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

(i) SECTION 10.—Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended—

(1) in the section heading, by striking "**DATA**" and inserting "**INFORMATION**";

(2) by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services";

(3) in subsection (b)—

(A) in the subsection heading, by striking "DATA" and inserting "INFORMATION";

(B) by striking "data" and inserting "information" in paragraph (1);

(C) by striking "data" and inserting "information" in paragraph (2)(A); and

(D) by striking "a data" and inserting "an information" in paragraph (2)(B); and

(4) in subsection (g), by striking "data" and inserting "information".

(j) SECTION 11.—Section 11(b)(2) of the Toxic Substances Control Act (15 U.S.C. 2610(b)(2)) is amended—

(1) by striking "data" ~~each place it appears~~ in subparagraph (E)

and inserting "information"; and

(2) in subparagraph (E), by striking "rule promulgated" and inserting "rule promulgated, order issued, or consent agreement entered into".

(k) SECTION 12.—Section 12(b)(1) of the Toxic Substances Control Act (15 U.S.C. 2611(b)(1)) is amended by striking "data" both places it appears and inserting "information".

(l) SECTION 15.—Section 15(1) of the Toxic Substances Control Act (15 U.S.C. 2614(1)) is amended by striking "(A) any rule" and all that follows through "or (D)" and inserting "any requirement of this title or any rule promulgated, order issued, or consent agreement entered into under this title, or".

(m) SECTION 19.—Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(A)—

(i) by striking "Not later than 60 days after the date of the promulgation of a rule under section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "Except as otherwise provided in this title, not later than 60 days after the date on which a rule is promulgated under this title, title II, or title IV, or the date on which an order is issued under section 4 or 6(i)(1),";

(ii) by striking "such rule" and inserting "such rule or order"; and

(iii) by striking "such a rule" and inserting "such a rule or order";

(B) in paragraph (1)(B)—

(i) by striking "Courts" and inserting "Except as otherwise provided in this title, courts"; and

(ii) by striking "subparagraph (A) or (B) of section 6(b)(1)" and inserting "this title, other than an order under section 4 or 6(i)(1),"; and

(C) in paragraph (2), by striking "rule-making record" and inserting "record"; and

(2) in subsection (b)—

(A) by striking "review a rule" and inserting "review a rule, or an order under section 4 or 6(i)(1),";

(B) by striking "such rule" and inserting "such rule or order";

(C) by striking "the rule" and inserting "the rule or order";

(D) by striking "new rule" each place it appears and inserting "new rule or order"; and

(E) by striking "modified rule" and inserting "modified rule or order"; and

(3) in subsection (c)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "a rule" and inserting "a rule or order"; and

(II) by striking "such rule" and inserting "such rule or order";

(ii) in subparagraph (B)—

(I) in the matter preceding clause (i), by striking "a rule" and inserting "a rule or order";

(II) by amending clause (i) to read as follows:

"(i) in the case of review of—

"(I) a rule under section 4(a), 5(b)(4), 6(a) (including review of the associated determination under section 6(b)(4)(A)), or 6(e), the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole; and

"(II) an order under section 4 or 6(i)(1), the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such order if the court finds that the

order is not supported by substantial evidence in the record taken as a whole; and"; and

(III) by striking clauses (ii) and (iii) and the matter after clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule or order, except as part of the record, taken as a whole."; and

(iii) by striking subparagraph (C); and

(B) in paragraph (2), by striking "any rule" and inserting "any rule or order".

(n) SECTION 20.—Section 20(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2619(a)(1)) is amended by striking "order issued under section 5" and inserting "order issued under section 4 or 5". ϕ*does this need to pull in 6(i) orders?¿* NO 6(i)

(o) SECTION 21.—Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "order under section 5(e) or (6)(b)(2)" and inserting "order under section 4 or 5(e) or (f)"; and ϕ*does this need to pull in 6(i) orders?¿* NO 6(i)

(2) in subsection (b)(1), by striking "order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "order under section 4 or 5(e) or (f)"; and

ϕdoes this need to pull in 6(i) orders?¿. NO 6(i)

(p) SECTION 24.—Section 24(b)(2)(B) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is amended—

(1) by inserting "and" at the end of clause (i);

(2) by striking clause (ii); and

(3) by redesignating clause (iii) as clause (ii).

(q) SECTION 26.—Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(2) in subsection (g)(1), by striking "data" and inserting "information".

(r) SECTION 27.—Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended—

[SUSTAINABLE CHEM UNDER DISCUSSION]

(1) by striking "Health, Education, and Welfare" and inserting "Health and Human Services";

(2) by striking "test data" both places it appears and inserting "information";

(3) by striking "rules promulgated" and inserting "rules, orders, or consent agreements"; and

(4) by striking "standards" and inserting "protocols and methodologies".

(s) SECTION 30.—Section 30(2) of the Toxic Substances Control Act (15 U.S.C. 2629(2)) is amended by striking "rule" and inserting "rule, order, or consent agreement".

SEC. 21. NO RETROACTIVITY.

Nothing in sections 1 through ¢20¿, or the amendments made by sections 1 through ¢20¿, shall be interpreted to apply retroactively to any State, Federal, or maritime legal action filed before the date of enactment of this Act.

SEC. 22. TREVOR'S LAW.

(a) PURPOSES.—The purposes of this section are—

(1) to provide the appropriate Federal agencies with the authority to help conduct investigations into potential cancer clusters;

(2) to ensure that Federal agencies have the authority to undertake actions to help address cancer clusters and factors that may contribute to the creation of potential cancer clusters; and

(3) to enable Federal agencies to coordinate with other Federal, State, and local agencies, institutes of higher education, and the public in investigating and addressing cancer clusters.

(b) DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–6. DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.

"(a) DEFINITIONS.—In this section:

"(1) CANCER CLUSTER.—The term 'cancer cluster' means the incidence of a particular cancer within a population group, a geographical area, and a period of time that is greater than expected for such group, area, and period.

"(2) PARTICULAR CANCER.—The term 'particular cancer' means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

"(3) POPULATION GROUP.—The term 'population group' means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

"(b) CRITERIA FOR DESIGNATION OF POTENTIAL CANCER CLUSTERS.—

"(1) DEVELOPMENT OF CRITERIA.—The Secretary shall develop criteria for the designation of potential cancer clusters.

"(2) REQUIREMENTS.—The criteria developed under paragraph (1) shall consider, as appropriate—

"(A) a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

"(B) scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

"(C) the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

"(D) the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

"(E) the time period over which the number of cases of a particular cancer, or the calculation of an expected number of cases, occurs.

"(c) GUIDELINES FOR INVESTIGATION OF POTENTIAL CANCER CLUSTERS.—The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments,

shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

"(1) recommend that investigations of cancer clusters—

"(A) use the criteria developed under subsection (b);

"(B) use the best available science; and

"(C) rely on a weight of the scientific evidence;

"(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

"(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

"(d) INVESTIGATION OF CANCER CLUSTERS.—

"(1) SECRETARY DISCRETION.—The Secretary—

"(A) in consultation with representatives of the relevant State and local health departments, shall consider whether it is appropriate to conduct an investigation of a potential cancer cluster; and

"(B) in conducting investigations shall have the discretion to prioritize certain potential cancer clusters, based on the availability of resources.

"(2) COORDINATION.—In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services and other Federal agencies, such as the Environmental Protection Agency.

"(3) BIOMONITORING.—In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

"(e) DUTIES.—The Secretary shall—

"(1) ensure that appropriate staff of agencies within the Department of Health and Human Services are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster from a State or local health authority;

"(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and

cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

"(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

"(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

"(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures Program of the Agency for Toxic Substances and Disease Registry.".

[DISCUSSION DRAFT]

SEC. ll. MANUFACTURING AND PROCESSING NOTICES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "Except as provided in" and inserting "(A) Except as provided in subparagraph (B) of this paragraph and";

(ii) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(iii) by striking all that follows "significant new use" and inserting a period; and

(iv) by adding at the end the following:

"(B) A person may take the actions described in subparagraph (A) if—

"(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with

subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of or imposed under subsection (b), (e), or (f); and

"(ii) the Administrator conducts a review of the notice and either—

"(I) makes a determination under paragraph (3)(A) and, as necessary, issues an order under subsection (f)(1); or

"(II) makes a determination under paragraph (3)(B) and issues an order under subsection (e)(1)(B).''; and

(B) by adding at the end the following new paragraphs:

"(3) REVIEW AND DETERMINATION.—~~Not later than 90 days after receipt of a notice under paragraph (1), subject to section 18,~~ Before the end of the applicable review period, subject to section 18, the Administrator shall review such notice and

the Administrator shall review such notice and—

Commented [A1]: Redundant text

"(A) determine whether the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or sus-

ceptible subpopulation identified as relevant by the Administrator under the conditions of use, and take applicable action under subsection (f) or (g); or

"(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (e).

"(4) FAILURE TO RENDER DETERMINATION.—

"(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Administrator shall not be relieved of any requirement to make such determination.

"(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsections (b) or (e) or has otherwise

unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review.

"(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

"(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

"(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.";

(2) in subsection (b)—

(A) in the subsection heading, by striking "TEST DATA" and inserting "INFORMATION";

(B) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information"; and

(II) by striking "such data" and inserting "such information"; and

(ii) in subparagraph (B), by striking "test data" and inserting "information";

(C) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information";

(II) by striking "shall" and inserting "may"; and

(III) by striking "data prescribed" and inserting "information prescribed"; and

(ii) in subparagraph (B)—

(I) by striking "Data" and inserting "Information";

(II) by striking "data" both places it appears and inserting "information"; and

(III) by striking "show" and inserting "shows";

(D) in paragraph (3)—

(i) by striking "Data" and inserting "Information"; and

(ii) by striking "paragraph (1) or (2)" and inserting "paragraph (1) or (2) of this subsection or under subsection (e)"; and

(E) in paragraph (4)—

(i) in subparagraph (A)(i), by inserting ", without consideration of costs or other nonrisk factors" after "health or the environment"; and

(ii) in subparagraph (C), by striking ", except that" and all that follows through "subparagraph (A)";

(3) in subsection (c)—

(A) in the subsection heading, by inserting "AND REVIEW" after "NOTICE"; and

(B) by striking "before which" and all that follows through "subsection may begin";

(4) in subsection (d)—

(A) by striking "test data" in paragraph (1)(B) and inserting "information";

(B) by striking "data" each place it appears in paragraph (1)(C) and paragraph (2) and inserting "information";

(C) in paragraph (2)(B), by striking "uses or intended uses of such substance" and inserting "uses of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator"; and

(D) in paragraph (3)—

(i) by striking "for which the notification period prescribed in subsection (a), (b), or (c)" and inserting "for which the applicable review period"; and

(ii) by striking "such notification period" and inserting "such period";

(5) by amending subsection (e) to read as follows:

"(e) REGULATION WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1) If the Administrator determines that the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) for a chemical substance or significant new use with respect to which notice is required by subsection (a)—

"(A) the Administrator—

"(i) shall provide an opportunity for the submitter of the notice to submit the additional information within the applicable review period;

"(ii) may, by agreement with the submitter, extend the applicable review period for a reasonable time to allow the development and submission of the additional information including under section 4; and

"(iii) ~~on receipt of the additional information complying with a rule, testing consent agreement, or order issued under section 4, may extend the review period not more than 90 days to make a decision~~; not later than 90 days after receipt of sufficient information under clause (i) or information complying with a rule, consent agreement, or order under section 4, shall make the determination under subsection (a)(3)(A)" and

"(B) the Administrator may issue an order to take effect on the expiration of the applicable review period to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, or any combination of such activities, sufficient to allay the Administrator's initial concern that, in the absence of sufficient information, the substance or significant new use may present an unreasonable risk of injury to health or the environ-

Commented [A2]: Shouldn't this just say "under clause (i) or (ii)??

Commented [A3]: This changed text seems problematic because it does not provide for extension of the review period and therefore leaves open the question of whether the determination described in (iii) occurs after the review period.

Both of these issues could be addressed by rewording the new text as follows: "not later than 90 days after receipt of sufficient information under clause (i) or (ii), which shall extend the review period by 90 days, shall make the determination under subsection (a)(3)(A)."

ment.

"(2) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other nonrisk factors.

"(3) If the Administrator issues an order under paragraph (1), the submitter of the notice under subsection (a) may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection only in compliance with the restrictions specified in the order.

"(4) Not later than 90 days after issuing an order under paragraph (1), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(5) An order may not be issued under paragraph (1) respecting a chemical substance—

"(A) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c); and

"(B) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.";

(6) by amending subsection (f) to read as follows:

"(f) PROTECTION AGAINST POTENTIAL UNREASONABLE RISKS.—

"(1) ORDERS.—If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may present an unreasonable risk of injury to health or the environment in accordance with subsection (a)(3)(A)—

"(A) the Administrator shall issue an order, to take effect on or before the expiration of the applicable review period to prohibit or otherwise restrict the manufacture, processing,

distribution in commerce, use, or disposal of the chemical substance, or of the chemical substance for a significant new use, sufficient to allay the Administrator's initial concern that the substance or significant new use may present an unreasonable risk of injury to health or the environment;

"(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection except in compliance with the restrictions specified in the order; and

"(C) not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(2) SELECTING PROHIBITIONS AND RESTRICTIONS.—In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other nonrisk factors, and such an order ~~shall include a~~ may include any requirement described in section 6(a).

"(3) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance that is subject to the requirements of this subsection and that the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance to the extent practicable.

"(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the

Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.";

(7) by amending subsection (g) to read as follows:

"(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment is not warranted, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture ~~for commercial purposes~~ of the chemical substance or manufacture or processing ~~for a commercial purpose~~ for a significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.";

(8) in subsection (h)—

(A) in paragraph (1)(A), by inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific uses identified in the application" after "health or the environment";

(B) in paragraph (1)(B), by striking "appropriate" and inserting "warranted"

(B) in paragraph (2), by striking "data" each place it appears and inserting "information"; and

(C) in paragraph (4), by striking ". A rule promulgated" and all that follows through "section 6(c)" and inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use"; and

(9) by amending subsection (i) to read as follows:

"(i) DEFINITIONS.—(1) For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.

"(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.

"(3) For purposes of this section, the term 'applicable

review period' means the period starting on the date the

Administrator receives a notice under subsection (a)(1) and ending ~~on the date the Administrator makes a determination under subsection (a)(3)(A), as extended pursuant to subsection (c) or (e)(1)(A).~~ and ending on the date that is 90 days thereafter, as extended pursuant to subsection (b), (c) or (e).".

Commented [A4]: Per comment above, (e)(1)(A)(i) and (ii) provide for extension, but e1Aiii, which gives EPA 90 days after receipt of information to render a determination, does not expressly create and extension of the review period.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 8:38:52 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA request on Sec. 5

Jonathan – will do. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 19, 2016 4:38 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: EPA TA request on Sec. 5

A short call would also be helpful. Let us know when they can do so. thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 19, 2016 4:37 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: EPA TA request on Sec. 5

Jonathan – yes, thanks for flagging. We agree and are developing some additional revised TA to send shortly. I'll share this with folks to make sure we're looking at the right version. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 19, 2016 4:35 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: EPA TA request on Sec. 5

Hi Sven, it isn't clear to us that your team reviewed the right Sec. 5 document that we received from HLC. I'm reattaching that section 5 along with comments we put on your TA.

We really want your take on the changes made to subsection (e)(1)(A) in the case of EPA requiring testing. The latest draft says the review period in such case can only be extended by agreement with the submitter, which makes no sense to us. Folks also point to subsection (c)'s "good cause" language, but extensions there are limited to a maximum of 90 days which may not always be enough.

We think this is the only unresolved issue.

Can we also get on the phone with you as soon as your team is available for a quick question on Sec. 5?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2016 10:56:58 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it- checking

On Mar 16, 2016, at 6:37 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does this work for 14(c)(3)

> (1) <!--[if !supportLists]--><!--[endif]-->BAN OR PHASE-OUT.—(A) If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any information under this section with respect to the chemical substance shall no longer apply, subject to subsections (g)(1) (g)(2) and (g)(3).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 4:43 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 1:16 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

(c) Information Not Protected From Disclosure.—
(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:
(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
(i) IN GENERAL.—Subject to clause (ii)—
(I) any health and safety study that is submitted under this Act with respect to—
(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or
(bb) any chemical substance or mixture for which—
(AA) testing is required under section 4; or
(BB) a notification is required under section 5; or
(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).
(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—
(I) a process used in the manufacturing or processing of a chemical substance or mixture; or
(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.
(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:
(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).
(ii) A safety assessment developed, or a safety determination made, under section 6.
(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.
(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.
(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 1:13 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,
This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 10:32 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/23/2016 2:02:20 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA - another 6(a) alternative

Michal- It was not in response to that one. It was in response to the email at 9:56 am yesterday with three similar variants. Please let me know if any additional questions. Thanks,
Sven

On Mar 23, 2016, at 9:13 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just making sure that the note w alternatives that you sent last night was not in response to this one. Basically just want confirmation that the 2 alternatives I have pasted below both work for you and don't insert costs into anything?

> (a) <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image002.png><!--[endif]--> <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image004.png><!--[endif]--> <!--[if !vml]--><image005.png><!--[endif]--> <!--[if !vml]--><image001.png><!--[endif]-->SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

SCOPE OF REGULATION—If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, then the Administrator shall by rule, and subject to section 18, apply one or more of the following requirements to such substance or mixture to the extent necessary [to ensure/so] that the chemical substance does not present such unreasonable risk, as determined in accordance with subsection (b)(4)(A), under the intended conditions of use. In selecting the particular requirement or requirements to be applied pursuant to this subsection, the Administrator shall, in accordance with subsection (c)(2), take into consideration costs and other factors in choosing among the requirements evaluated.

Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 22, 2016 3:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA - another 6(a) alternative

Michal,
This TA responds to the request to review a 6(a) option dealing with section 18 and (c)(2) references.

> OPTION 2
>
> (a) <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image002.png><!--[endif]--> <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image004.png><!--[endif]--> <!--[if !vml]--><image005.png><!--[endif]--> <!--[if !vml]--><image001.png><!--[endif]-->SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

The changes you suggest do help address the specific issue we identified in our most recent TA -- the suggestion that section 18 and 6(c)(2) are on the same footing as limitations on EPA's authority. However, it does not address our long standing point that we think the reference to section 18 in this context is unnecessary and confusing. We understand your point about addressing Geier, but we think section 18 already does that (and if it doesn't, it's hard to see how a reference to it in section 6 would). The reference to section 18 in section 6(c) of the offer indicates that EPA's *authority* to promulgate rules under section 6(c) is limited in some way by section 18, which we do not understand to be your intent. Presumably, you mean to say that the *preemptive effect* of any rules EPA promulgates under section 6(c) is subject to section 18. (And, again, we don't really see the value of making such a point in section 6, since section 18 already provides that it governs the preemptive effect of section 6 rules, and has whatever effect it has with respect to Geier.)

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 21, 2016 12:17 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: another 6(a) alternative

> OPTION 2

(a) <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image002.png><!--[endif]--> <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image004.png><!--[endif]--> <!--[if !vml]--><image005.png><!--[endif]--> <!--[if !vml]--><image001.png><!--[endif]-->SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/17/2016 4:14:22 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - Section 4, parties to testing

Michal,
This TA responds to your followup request. Please leg me know if any additional questions. Thanks,
Sven

Simply striking "order, or consent agreement" from 4(b)(2)(A) wouldn't restore sense to the paragraph. Respecting rules issued under subsection (a), there would still remain a problem with 4(b)(2)(B) directing the reader to non-existent finding provisions ((a)(1)(A)(ii) and (a)(1)(B)(ii)).

More broadly, paragraph (4)(b)(2) is structured as a constraint on EPA's discretion to identify the scope of persons who would be subject to testing requirements for a particular rule, order, or consent agreement. Since the paragraph is a constraint on authority, it is not necessary in order for EPA to exercise its underlying testing authorities. Striking the paragraph would give EPA broad authority to require entities to conduct testing – including entities that are not manufacturers or processors of the chemical. Whether you should strike or update the paragraph depends on your the policy objectives.

On Feb 12, 2016, at 5:32 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

This is in reference to the EPA TA that pointed out that Section 4(b)(2) in what I sent you doesn't work with Senate 4(a).

Would it make sense to strike "order or CA" and then leave the provision related to rule authority? Is it necessary to specify who EPA can direct to test things at all (ie should we strike the whole thing)?

(2)(A) A rule, order, or consent agreement under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule, order, or consent agreement under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding de-scribed in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 10:14:40 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal - got it - checking. Thanks,
Sven

On Apr 23, 2016, at 6:13 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Ty – any issues w these edits?

- <!--[if !supportLists]--><!--[endif]-->Page 150 line 19 – Insert "the date on which" before "an order"
- <!--[if !supportLists]--><!--[endif]-->Page 150 line 19 – Insert "is issued" after "an order"

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 6:12 PM
To: Freedhoff, Michal (Markey)
Cc: Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,
Revised TA on section 19 with house changes annotated.

Section 19 – Sec. 19.XML comments
Page 1 – remove all brackets DONE

Page 1 line 6 to 19 -- consolidate this material in paragraph (a)(1), perhaps as a new (a)(1)(C). Per EPA TA to ensure that low priority decisions are covered by the judicial review provisions of subsection (c). DONE

Page 2 line 9 – remove brackets from "Except as otherwise provided by this title" DONE

Page 2 line 13 – remove brackets from " 6(i)(1)" DONE

Page 2 lines 18 to 25 – remove all brackets DONE

Page 3 line 6 – remove brackets from "6(i)(1)" DONE

Page 4, line 2– strike lines 2 through 21, and insert:
"by amending subsection (c)(1)(B)(i) to read: "(i) in the case of review of a rule under section 4(a), 5(b)(4), 6(a) (including review of the associated determination under section 6(b)(4)(A)) or 6(e), or an order under 6(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule or order if the court finds that the rule or order is not supported by substantial evidence in the record including any matter in the record taken as a whole;" DONE EXCEPT SUBSTANTIAL EVIDENCE DIRECTION FOR RULES AND ORDERS IS DIVIDED INTO SEPARATE SUBCLAUSES AND REVIEW OF TEST ORDERS UNDER SECTION 4 IS ADDED TO SUBSTANTIAL EVIDENCE REVIEW.

Page 5 line 7-8 – Strike the brackets before (iii) DONE

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On Apr 23, 2016, at 4:30 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just verifying before proceeding that you checked conforming edits at the end of the bill?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 4:29 PM
To: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,
While we continue to work on the TA requests on 14 and other sections, we wanted to pass along TA on house section 19 (4-23).

The House discussion draft leaves section 19 from current TSCA un-amended, except for the addition of judicial review of low-priority determinations. Thus, in contrast to the Senate bill and offer, it does not:

-- provide for judicial review of test orders under section 19

-- provide for judicial review of rules other than the rules currently enumerated in section 19

-- provide for judicial review of determinations that a chemical substance does not present unreasonable risk under section 19 (including the substantial evidence review the senate bill and offer would afford).

Note that this does not mean that these EPA actions will not be judicially reviewable. Rather, they would be reviewable in federal district court, rather than the court of appeals, and would be subject to the general federal 6-year review period, rather than the 60 days provided for in section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 2:34:42 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Section 4

Michal,
We are working on your last night's section 4 and meeting internally at 11 to go over it. Do you still want our comments on last night's version? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 05, 2016 10:29 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on Section 5 - early morning

Thank you. ai am re-drafting yet another section 4, pls stand by for that in the next hour or so I hope.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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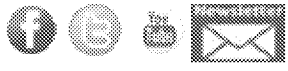

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 05, 2016 10:26 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on Section 5 - early morning

Michal – TA responding to your comments on section 5 attached. EPA comments in blue. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 05, 2016 6:00 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Section 5

Sven - comments in yellow are for you, changes marked with blank comment boxes and a couple in green for Dimitri. Pls take one more FAST look, need to get this to the House asap.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 5:57:54 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan, Definitely today – I'll let you know if any questions come up. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, April 13, 2016 1:57 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

No. I want them to do a good job. Hopefully COB today? let me know if not possible.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 13, 2016 1:56 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan, we're working on it – is there a drop dead time I should tell folks. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, April 13, 2016 1:52 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Checking in...

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 12, 2016 6:33 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Ok - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 12, 2016 6:32 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

Yes, thanks.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Tuesday, April 12, 2016 6:26 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
Got it – checking. Tomorrow ok? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 12, 2016 6:19 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Udall TSCA TA request on Industry nominated chemicals

Would appreciate thoughts on these edits/suggestions from EDF

Attached see our additions to EPA's rewrite of section 6(b)(4)(E), which:

- Include consistently missed deadlines for risk evaluations and rules as an additional critical indicator of EPA being overrun by industry requests;
- Preclude EPA from allocating disproportionately more resources to industry-requested chemicals, a concept that is already in the current text; and
- Require EPA, when selecting among industry requests, to give preference to those presenting greater concern using the criteria specified in the prioritization section.

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 12, 2016 2:02 PM

To: Richard Denison; Joanna (joannaslaney@gmail.com)
Subject: FW: Sen. Udall TSCA TA request on Industry nominated chemicals

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 11, 2016 5:20 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
This TA responds to the request on industry nominated chemicals language.

You requested a replacement for (b)(4)(E) that would eliminate the industry cap, but nonetheless provide comparable assurance that industry prioritizations would not overrun the resources necessary for EPA priorities.

We believe the following replacement for (E)(i) and (ii) would accomplish this objective. It operates by simply shutting down the pipeline for taking further industry requests if EPA falls behind on the expected pace of pursuing its own priorities. The edits are also attached as a redline to section 6 (attached).

(E) LIMITATION AND CRITERIA

"(i) If the Administrator's designation of priority substances or conduct of risk evaluations is insufficient to satisfy the requirements of paragraph (2)(A), (2)(B), or (2)(C), then the Administrator shall accept no further requests under subparagraph (C)(ii) until the requirements of paragraph (2)(A), (2)(B), and (2)(C) are all satisfied.

(ii) Requests for risk evaluations under subparagraph (C)(ii) shall be subject to public notice and comment and to the payment of fees pursuant to section 26(b)(3)(D), and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations,

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 11, 2016 1:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

Thanks Sven, I should have asked for you to draft to the Senate offer.

Possible to see that? Sorry.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Monday, April 11, 2016 1:33 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
This TA responds to the request on industry nominated chemicals.

QUESTION: EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Response:
The language in question is for the House offer. It would also work with minor adjustment for the House bill as passed. There is no min/max provision in the House bill as passed, so that part has to be deleted if you are modifying the House bill as passed.

House offer

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) and is not subject to paragraph (3)(C)(i)(I), unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

House bill as passed

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

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From: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Date: April 10, 2016 at 6:07:41 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Industry nominated chemicals

Hi Sven,

EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?